The impact of suboptimal asthma control and adherence to medication on health-related outcomes for children with asthma

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Statement of Originality

I, Katherine Marie Harris, confirm that the research included within this thesis is my own work or that where it has been carried out in collaboration with, or supported by others, that this is duly acknowledged below and my contribution indicated. Previously published material is also acknowledged below.

I attest that I have exercised reasonable care to ensure that the work is original, and does not to the best of my knowledge break any UK law, infringe any third party's copyright or other intellectual property right, or contain any confidential material.

I accept that the college has the right to use plagiarism detection software to check the electronic version of the thesis.

I confirm that this thesis has not been previously submitted for the award of a degree by this or any other university.

Signature: 

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1. The learning and outreach officer on the team assisted with the recruitment of schools for the study.
2. Dr Dylan Kneale, research officer at the Institute of Education, worked with me on the systematic review. Dr Kneale and I independently conducted the database searches, screened the identified papers, and independently extracted the data from the included studies for analysis. Dr Kneale ran the statistical analyses for the review and contributed to the write-up of the Cochrane review.
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Data sharing and audit:

All of the data that has been used for the purposes of this thesis has been stored in accordance with the research protocol and ethical recommendations. All of the questionnaire data files have a timestamp, and are stored securely on a password protected document on a Queen Mary University of London (QMUL) computer. The focus group data has been transcribed externally (a copy of the confidentiality agreement can be found in the appendices) and all transcriptions and original voice recordings are stored on a QMUL computer behind password protected firewalls. This data can be accessed via a password for the purposes of audit. The systematic review data is stored on the EPPI-Reviewer server, and can be accessed by members of the review team via a password protected user name and password server.

Abstract

Background:

Asthma is the most common long-term condition in children in the United Kingdom (UK). Asthma-related hospitalisations and mortality are disproportionally higher in the UK, compared with other European countries, however the reasons for this disparity remain unclear. A putative explanation is that that prevalence of suboptimal asthma control in children in the UK is higher than in continental Europe. If this is indeed correct, then the drivers of suboptimal control, such as poor adherence to therapy resulting from poor understanding of the role of preventer medication (inhaled corticosteroids (ICS)) in UK children would be of significant clinical interest. Therefore, in this thesis, I sought to first identify the levels of asthma control and medication adherence in a non-random sample of London secondary school children. Then, I used focus groups to further highlight the barriers to good medication adherence, and generate insights into potential solutions. To achieve these aims, I developed and implemented an online questionnaire to be delivered in schools, which included the validated Asthma Control Test (ACT).

Methods:

This thesis is divided into three main sections. The first and second sections include original data from an observational research study, which collected data about asthma control, from 24 London secondary schools between December 2014 and March 2016. The aim of the first section was to assess current levels of asthma control and medication adherence among children with asthma in London secondary schools. Data were collected using an online questionnaire, which included the validated ACT to measure asthma control, as well as additional questions about knowledge, healthcare use, medication use, school attendance, lifestyle and emotion and behaviour, using the validated Me and My School (M&MS) questionnaire. The second section of this thesis includes data generated from six focus groups, conducted in four London secondary schools with 56 students. In order to generate data to inform future interventions, discussions focused on the barriers to medication adherence among teenagers, and how these barriers could be addressed.

The third section comprises a systematic review of school-based self-management interventions for children with asthma. The review uses a mixed-methods approach, and includes both quantitative and qualitative study data. A process evaluation is also included, to identify intervention elements that are associated with implementation success.

Results:

766 children with asthma from 24 schools were surveyed. Almost half of the students (45.7%; n = 350) had poor asthma control by ACT score. Adherence with asthma medication was low, regardless of asthma control (56.2% self-reported forgetting to use their ICS "preventer" inhaler; 29% self-reported not using their SABA "reliever" inhaler when they needed it, at least some of the time). Health care involvement was relatively high, with at least one unplanned GP visit, due to asthma in the previous four weeks, reported by 28.1% of students; at least one unplanned hospital visit was self-reported by 15.7% of students; and at least one unplanned school nurse visit due to asthma was self-reported by 16% of students. At least one whole school absence was reported by 20.9% of students. Unplanned medical care and school absences were higher among children with poor asthma control, according to the ACT.

Themes from focus groups suggested that social stigma, fear of embarrassment, forgetfulness, and incorrect attitudes towards medication were all contributory factors to poor medication adherence. Communications with healthcare professionals were also identified as key unmet needs of teenagers with asthma.

The findings from the meta-analyses, included in the systematic review of school-based self-management interventions, showed that such interventions were effective in improving several outcomes, largely related to healthcare use. These included hospitalisations, emergency department (ED) visits, and health-related quality of life. There was no evidence that school-based interventions improved school absences, experiences of day and night time symptoms, or the use of medication. The findings from the analysis of the process evaluation studies showed that a theoretical framework is important in the development of a successful intervention.

Conclusions:

First, in a large non-random sample of secondary school children with asthma, the proportion of children with suboptimal control is worryingly high, and this is associated with general poor adherence to prescribed therapy asthma. Second, focus groups identified practical and social barriers to good adherence, that should be addressed in future studies. Third, previous studies suggest that school based interventions are effective in reducing incidences of unplanned and urgent healthcare use. The systematic review included studies that included relatively hard-to-reach populations, suggesting that such interventions may be effective across diverse populations, including those considered hard-to-reach.

The findings in this thesis informed the development of a school-based self-management intervention, to be piloted in London secondary schools, and an NIHR-funded global research group award on improving asthma control in African children.

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List of Abbreviations

The following table comprises a list of all the abbreviations included throughout this thesis, and the page number on which they first appear.

Abbreviation	Meaning	Page
CLAHRC	Collaboration for Leadership in Applied Health Research and Care	2
NIHR	National Institute for Health Research	2
QMUL	Queen Mary University of London	5
M&MS	Me and My School	6
ED	Emergency Department	7
ICS	Inhaled Corticosteroids	19
GINA	Global Initiative for Asthma	19
LABA	Long-Acting Beta-Agonist	19
PCD	Primary Ciliary Dysplasia	19
UK	United Kingdom	20
GP	General Practitioner	20
NHS	National Health Service	20
SABA	Short-Acting Beta-Agonist	25
ACT	Asthma Control Test	21
RCT	Randomised Controlled Trial	23
BTS	British Thoracic Society	26
SIGN	Scottish Intercollegiate Guidelines Network	26
ISAAC	International Study of Asthma and Allergies in Children	28
WHO	World Health Organisation	31
FEV_1	Forced Expiratory Volume	37
AIRE	Asthma Insights and Reality in Europe	38
RCP	Royal College of Physicians	39
CACT	Childhood Asthma Control Test	40
AQLQ	Asthma Quality of Life Questionnaire	40
OR	Odds Ratios	40
PAQLQ	Paediatric Asthma Quality of Life Questionnaire	41
SES	Socioeconomic Status	48
PPI	Patient and Public Involvement	65
COTC	Centre of the Cell	66
PE	Physical Education	95
QCA	Qualitative Comparative Analysis	140
MRC	Medical Research Council	145
HRQoL	Health-Related Quality of Life	149
SoF	Summary of Findings	159
SMD	Standardised Mean Differences	162
CI	Confidence Interval	162
MD	Mean Differences	164
ICC	Intracluster Coefficient	164
SE	Standard Error	166
fsQCA	Fuzzy Set Qualitative Comparative Analysis	167
GRADE	Grading of Recommendations Assessment Development and Evaluation	168

Chapter 1. Introduction

1.1 Overall rationale

Asthma is a common chronic respiratory condition that affects over 300 million children and adults worldwide [1]. Symptoms of asthma include episodic feelings of breathlessness, wheeze, and cough, tightness in the chest and difficulty engaging in daily activities, including physical exercise. A major goal of therapy is to achieve good control of asthma symptoms. However, despite diagnosis and initial treatment, some patients remain symptomatic. In these patients, treatment may therefore need to be escalated (i.e. stepped up). For this reason, the definition of asthma severity by the Global Initiative for Asthma (GINA) combines both symptoms and current therapeutic status. By the GINA classification, patients with "mild" asthma are well controlled with reliever medication on an as needs basis, or with a low-dose inhaled corticosteroid inhaler (ICS). "Moderate" asthma is well controlled with inhaled low-dose ICS $\pm$ long acting beta 2 agonist (LABA), whereas "severe" asthma can be well controlled on high dose ICS $\pm$ LABA). Severe asthma, in particular, should only be considered after the exclusion of other explanations, such as poor inhaler technique; poor medication adherence; incorrect diagnosis of asthma (some children have rare conditions such as primary ciliary dysplasia (PCD)); comorbidities; and ongoing exposure to asthma triggers [2]. The severity of asthma symptoms varies widely between individuals, and in the most severe cases, acute or chronic episodes of airway narrowing can result in hospitalisation or, rarely, death.

Airway narrowing during exacerbations of asthma, where children become acutely breathless, are due to the contraction of smooth muscle and inflammation of the lining of the airways. According to GINA, the long-term goal of asthma management is to achieve good day to day asthma control in order to reduce the number of asthma symptoms and exacerbations experienced by all asthmatics [2]. Asthma, particularly if it is poorly controlled, can considerably impact on daily functioning and quality of life for asthma sufferers; particularly in their ability to take part in everyday activities, and, for children, their capacity to fully engage in school lessons or work. Clinicians therefore take asthma control seriously, since it is an indicator of future asthma exacerbations [3]; i.e. poor control of asthma increases the risk of asthma attacks, and is used as a guide for the need to step up or step down inhaler therapy. In this context, asthma control can

be considered as a way of describing the extent to which the various clinically relevant symptoms of asthma have been reduced, or removed completely, as a result of diagnosis and subsequent treatment [4]. Clearly, there are several domains that contribute to the assessment of asthma control, but the presence or absence of symptoms and the extent to which an individual can engage in everyday activities is a key component. In poorly controlled cases, it is a greater burden of asthma symptoms and more subjective (and objective) experience of asthma exacerbations [4]. The result of poor asthma control is not only of significance to the patient (child) themselves, but also to the National Health Service (NHS), with increased need for unplanned General Practitioner (GP) and hospital emergency department visits [5].

In the United Kingdom (UK), asthma remains a major problem in children. Approximately one in eleven children and young people in the UK have a diagnosis of asthma, and the prevalence of asthma among children and young people in the UK is higher than elsewhere in Europe. According to Asthma UK, three children in every school classroom are living with asthma, although many more will have experience the symptoms of asthma during their lifetime [6]. The effect of asthma on UK children at school is not well reported. However, research by Moonie *et al* [7] in the US in 2006, reported that children with asthma, particularly those with severe or persistent asthma, are more likely to have time off school, compared to their peers without asthma [7]. Over the course of one academic year, students with asthma in the study of Moonie *et al* [7] averaged 9.5 days absent from school; an additional 1.5 days more than their peers. Further, 1537 school absences were tracked, and the data showed that 31% of absences were directly as a result of asthma symptoms [7]. Whether these results are generalizable to children attending UK schools, remains unclear.

Adherence to medication is defined as the extent to which an individual abides by the treatment plan set by their doctor for any given condition [8]. Possible factors which may predict adherence behaviours include obtaining new prescriptions for medication, social concerns, and attitudes and beliefs towards the medication. Medication adherence is considered to be associated with hospitalisations and mortality [9], and tends to be more often seen in patients with poorer asthma control, since suboptimal adherence in a child with very mild asthma may not necessarily result in acute worsening of symptoms. Currently, there are no specific guidelines for what constitutes

nonadherence in asthma treatment; however Strandbygaard *et al* suggest that it is applied to cases where less than 80% of medication is taken as prescribed [10]. Although similar in meaning, adherence is generally preferred to the term compliance, due to the negative connotations associated with compliance, in placing full responsibility with the medical provider, rather than giving some responsibility to the patient [11]. Throughout this thesis, I have referred to medication adherence as meaning cases where children are taking (or not taking) their medication as prescribed by their GP.

Maintaining good management of asthma symptoms, and achieving good asthma control, can reduce the negative impact of asthma on quality of life, as well as ease the economic burden placed on healthcare services. According to GINA, good asthma control is characterised by minimal or no day or night-time symptoms, however healthcare professionals in the UK recognise that this may not always be possible in some more severe cases [12]. It is reasonable to assume that achieving good asthma control in children and young people at school will positively impact on social and educational development, through minimising the likelihood of missed learning and social opportunities as a result of asthma symptoms. One component of achieving good control is supporting self-management – a process that involves the patient taking responsibility for their asthma away from the clinical environment. It involves working in partnership with their doctor to successfully manage the symptoms of asthma at home. Self-management will be discussed further in chapter two.

1.2 Hypothesis, Aims and Objectives

Hypothesis

I hypothesise, from the evidence discussed above, and subsequently in Chapter three, where I discuss the findings of my school-based questionnaire for children with asthma, that there is a high prevalence of poor asthma control, as measured by the ACT (Asthma Control Test), in children and young people with asthma attending secondary schools in London. I further hypothesise that children with poor asthma control will have (i) higher rates of school absences; (ii) high rates of unplanned GP and hospital visits, due to their asthma, and (iii) poorer quality of

life, compared to students with good asthma control. I also hypothesise that one reason for the high prevalence of poor control is that the majority of children with asthma have suboptimal knowledge of prescribed asthma medication, and suboptimal adherence to prescribed medication. My null hypothesis is that there is no significant difference in knowledge, adherence to prescribed medications, school attendance and healthcare use between the children and young people with asthma with good and poor control, as assessed using the ACT.

Aims and Objectives

To address these hypotheses, I sought in this thesis to address three specific questions:

i. How well controlled is asthma among children and young people in London secondary schools?
ii. How well is asthma medication adhered to among children and young people in London secondary schools, and what are the barriers to achieving good adherence?
iii. What is the evidence that self-management interventions are effective, according to the current literature?

To answer the first question, I sought to identify current levels of asthma control and adherence to medication among secondary school children in London, using an online assessment tool, including the Asthma Control Test (ACT). I also sought to record unplanned medical visits, school attendance, and emotional and behavioural wellbeing - comparing their frequency between students with asthma who had good and poor asthma control, according to the ACT. To answer the second question, I sought to explore putative barriers to suboptimal adherence among teenagers, using free-text data within the online assessment tool, and subsequent focus groups. I aimed for these data to inform the development of a school-based self-management intervention, to be implemented in secondary schools across London – an intervention aimed at improving asthma control in children and young people.

To answer the third question, I sought to conduct a systematic review of school-based self-management intervention for children with asthma. I planned to use the findings of the systematic

review, along with the findings from the online assessment tool and subsequent focus groups, to justify the development of a school-based intervention.

1.3 Overall structure to address hypothesis and aims

Chapter **ONE** introduces the research, including the rationale for the study. The research questions, and the primary and secondary aims are also described, accompanied by an overview of how the aims will be achieved. Chapter one also includes the research hypothesis.

Chapter **TWO** delivers the general background to paediatric asthma, including a comparison of global statistics for asthma prevalence, morbidity and mortality. The Chapter continues with a review of asthma control, including how it is measured, and the success of these measurements in assessing asthma control, as well as the determinants of poor control. Also included is an evaluation of the prevalence of poor asthma control across different countries. The Chapter ends with an overview of asthma management among children and young people in schools.

Chapter **THREE** discusses the school-based survey, including the development of the online assessment tool, the methods that were used to implement the tool, and the findings from the pilot study and the main trial.

Chapter **FOUR** includes the rationale for the qualitative component of the study and an overview of the development of the focus groups, and concludes with the main findings from the qualitative work.

Chapter **FIVE** consists of a mixed-methods systematic review of school-based self-management interventions for children with asthma. This review includes a process evaluation, to ascertain the configurations of interventions that contribute towards its success, as well as a meta-analysis of Randomised Controlled Trials (RCT).

Chapter **SIX** brings together the content of this thesis and discusses the main findings, and the implications of these findings for both research and practice. It also discusses the challenges and successes of this thesis, as well as the plans for the next steps and future research, and closes with an overview of the final conclusions from this thesis.

Chapter 2. Paediatric Asthma: A Continuing Problem

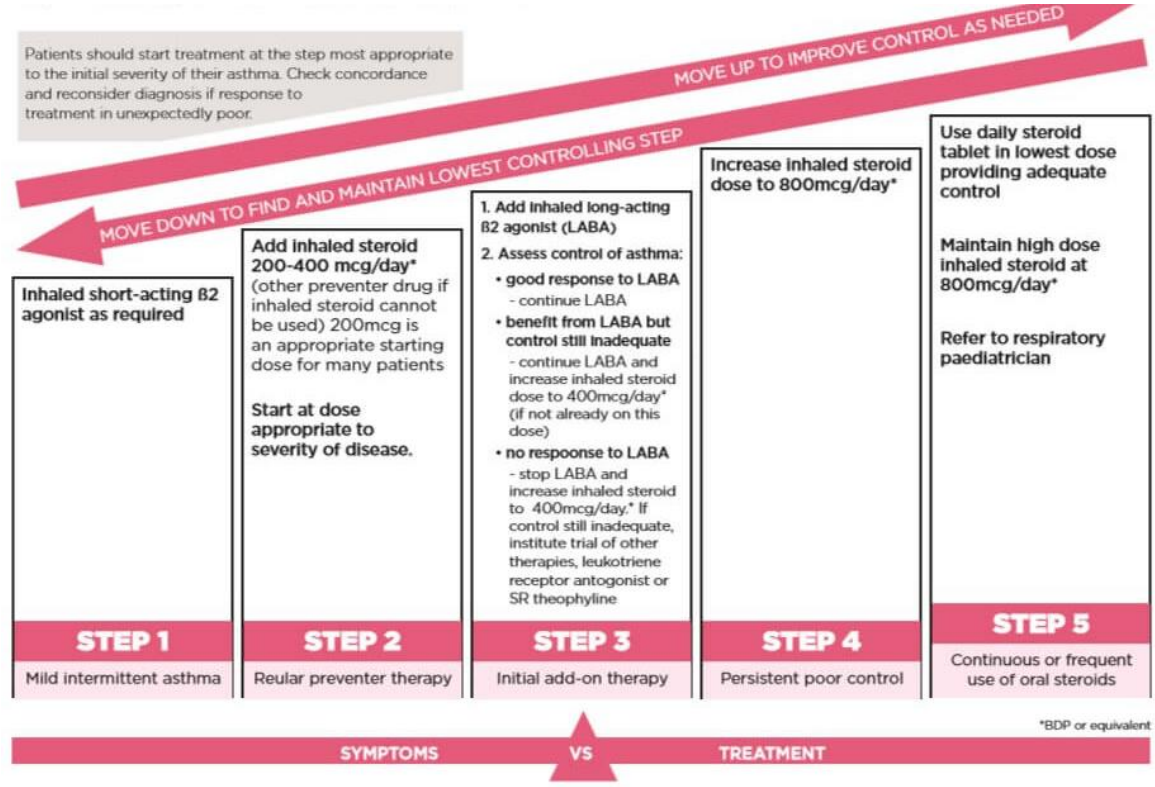
In this chapter I will discuss the prevalence of paediatric asthma worldwide, and asthma-related morbidity and mortality in the UK, Europe and worldwide. Asthma control, and the determinants of poor asthma control, will also be discussed, including the current ways in which control is assessed clinically. This evidence specifically addresses some of the issues that remain to be addressed on paediatric asthma in the UK, for asthma sufferers and healthcare professionals.

2.1 Background to Paediatric Asthma

Asthma, derived from the Greek term meaning 'short of breath', has been a respiratory condition since the late nineteenth century, following the work of Doctor Salter, who himself was an asthma sufferer [13]. In the early half of the 20th century, asthma was treated using medicines, including β_2-adrenoceptor agonists and salbutamol, initially as over the counter medications. Following an epidemic in the 1960s, which saw a sharp rise in the number of asthma deaths reported across the United Kingdom (UK) and Australia, a clearer understanding emerged of the immunology of asthma, and how it operated as an inflammatory disorder.

There is currently no 'gold-standard' diagnostic test available for asthma; instead it is diagnosed by a physician through the presence and pattern of respiratory symptoms, repeated lung function tests, and a patients' response to medication [14]. The close association of these clinical variables does not necessarily mean that the underlying pathology is similar. Indeed, the recent Lancet asthma commission (discussed below) concluded that the term "asthma", with its implication that it is a single pathology, should be discarded, and researchers and clinicians should in future focus on "treatable traits" [15]. Irrespective of the underlying pathology, clinical symptoms of asthma are normally treated using an inhaler and a spacer. Although inhaled treatments vary according to individual patients, asthma medication typically include (i) inhaled corticosteroids (ICS), which have no immediate effect on symptoms, but suppress the inflammation that leads to bronchoconstriction, long-acting beta-agonists (LABA), and taken twice daily to provide medium term bronchodilation, and (ii) short-acting beta-agonists (SABA), which directly dilate the bronchi of the lower airway and rapidly relieve the symptoms of asthma. Some children with well controlled asthma may require a SABA inhaler, but the majority will require both a SABA and

ICS. The British Thoracic Society/Scottish Intercollegiate Guidelines Network (BTS/SIGN) guidelines have previously introduced a stepwise approach to asthma management, to help patients to achieve optimal control of their asthma [16]. The stepwise approach is shown in figure



one.

Figure 1. BTS/SIGN stepwise approach to asthma management [16]

2.2 Prevalence, Mortality and Economic Impact

2.2.1 Asthma Prevalence

There is a discernible geographic variation in the global prevalence of asthma, and westernised countries report a higher prevalence of the disease, compared with the rest of the world. However, the global prevalence of asthma is continuing to rise as non-Western countries become increasingly more westernised. As a result, Masoli *et al* 2004 have reported that there could be an additional 100 million people living with asthma around the world by 2025 [1]. As seen in figure two (below), the prevalence of asthma in the UK and Republic of Ireland is disproportionately high, compared with standardised data for the rest of Europe [17]. The Global Burden of Asthma Report conveyed that an estimated 16.1% of people living in the UK and Ireland have received a clinical diagnosis of asthma, out of a total population of 63.3 million people [1]. This is compared

to Western Europe, where the reported asthma prevalence is much lower, estimated to be approximately 6% of the total population of 291 million people. It is also likely that many more people are living with the symptoms of asthma, without a formal diagnosis from a clinician. The prevalence of asthma in the UK is seemingly comparable with the figures reported across North America, Australia and New Zealand. According to Bousquet *et al* 2010, in these regions, the prevalence of asthma reportedly stands at 10%, 14.7% and 15.1%, respectively [18].

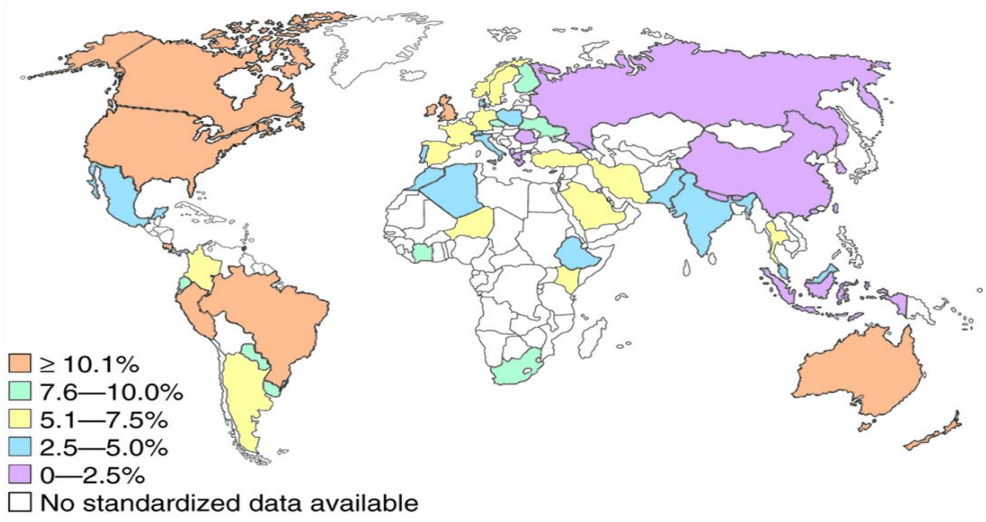


Figure 2. Global asthma prevalence [17]

In contrast, the prevalence of asthma in developing countries has historically been much lower than the Western world. However, the prevalence of asthma in less economically developed countries is growing, and the subsequent burden of asthma is far greater in these areas, due to a lack of available resources to teach patients about asthma management, a reduced infrastructure and restricted access to basic medications and clinical care [1]. In less economically developed regions, such as North Africa and Central America, approximately 3.9% of the population (7.7 million people) and 3.8% of the population (5.2 million people) are living with asthma, respectively [17], however complications from asthma are much higher in these regions. A recent report looking at the incidence of atopic disorders across Africa noted that the spread of asthma was highest in urban areas, where a higher standard of living was commonplace [19], providing further evidence that the prevalence of asthma is greater in urbanised regions.

Sharp increases in the global prevalence of childhood asthma are also becoming particularly noticeable [17]. Asthma generally presents itself much earlier in life than other respiratory conditions, and typically affects more children than adults. Asthma is one of the most prominent

non-communicable diseases among children internationally, and is the most common chronic condition in children in the UK. In recent years, an anticipated 308 million children worldwide, equivalent to 14% of the global paediatric population, will have experienced asthma symptoms at least once during their lifetime [20], however this figure is likely to be higher than the data suggests. According to the International Study of Asthma and Allergies in Childhood (ISAAC) questionnaire, paediatric asthma is also much higher in developed countries. Outside of Western Europe, Costa Rica and New Zealand recorded the highest prevalence of paediatric asthma. Approximately 27.3% and 26.7% of children aged 13-14 years, respectively, had experienced asthma symptoms in the twelve months prior to the study [21]. The lowest prevalence, recorded in Albania, was 3.4%. Similar trends were also seen among children aged 6-7 years.

It is unclear why the prevalence of asthma is so much higher in urbanised countries. One explanation could be that advancements in medicine have made diagnostic screening for asthma and access to screening easier in more economically developed countries. In the absence of a standardised diagnostic tool for asthma, it could be that more westernised countries, such as the UK, have more sophisticated screening techniques that may diagnose asthma more readily, compared with less economically developed countries. Conversely, children in westernised countries with easy access to medical care may be at increased risk of an over-diagnosis of asthma - leading to a higher recorded prevalence. A further explanation could be variations in the measuring and recording of asthma cases in different countries. For example, different survey methods used by studies such as the International Study of Asthma and Allergies in Childhood (ISAAC) [22] and the World Health Survey [23] may contribute towards differences in the statistics from different areas. Ideally we need a standardised measure for assessing the prevalence of asthma worldwide to help compare trends in asthma prevalence across different countries. A third, and not mutually exclusive, explanation is that differences in the mix of asthma phenotypes may alter the way asthma is perceived in different countries. According to the Lancet asthma commission [15], at least two clinical asthma phenotypes exist: extrinsic asthma, due to environmental allergens and associated with younger age of onset, atopy and the presence of other allergic diseases; and intrinsic asthma, due to factors inside the body and associated with older age and the absence of atopy. If one phenotype resulted in more attacks and hospital admissions,

then the clinical burden of asthma may be perceived as higher than a country where the dominant phenotype leads to mild chronic symptoms, but fewer attacks.

In the UK, 1.1million children (one in eleven) are currently thought to be living with asthma. This equates to an average of three children in every school classroom, according to Asthma UK, 2014 [6]. Notwithstanding the issues related to assessing prevalence, discussed above, the prevalence of asthma symptoms among children in the UK is markedly higher than other western European countries, and are comparable with figures seen in Australia and New Zealand. According to the most recent phase of the ISAAC study, conducted between 2000 and 2003 by Asher *et al*, the prevalence of asthma symptoms among 13-14 year olds in the UK was 20.9%, compared with Belgium, which reported the lowest prevalence at 8.3%. The reasons for the disproportionally high prevalence in the UK, compared with other European countries, remains largely unclear. If it is a true increase, then one explanation is that there has been a rise in the tendency for allergic sensitisation – a major risk factor for the atopic asthma phenotype. Alternatively the increase, may be due to increased exposure to environmental factors, such as air pollution, which is much higher in urbanised areas [24], and is associated with both new onset asthma and exacerbations in established asthmatics.

The ever-changing global prevalence of asthma does still raise questions over the accuracy of reporting, and whether or not asthma is over or under-diagnosed; particularly as many countries have seen a rapid increase in prevalence over time. In the absence of a standardised diagnostic tool in clinical practice, it is difficult to know whether all asthmatic diagnoses are appropriate. Historically, asthma has tended to be under-diagnosed, leading to patients not receiving their required treatment and notable increases in morbidity and mortality rates. However, more recently, some researchers have suggested that some patients, for example those with cough alone, or shortness of breath on exercise due to poor fitness, may be diagnosed with asthma [25], in an attempt to not miss any patients with true asthma. Potential over-diagnosis of asthma, has significant implications for healthcare systems, as well as for patients. It imposes an additional financial strain on healthcare systems, through unnecessary medical appointments, care and prescribing unnecessary treatment. Conversely, for many patients with symptoms of asthma, a failure to recognise true symptoms may lead to poorer long-term outcomes, and increased risk of

hospitalisation [26]. For example, in the UK, under-diagnosis results in more absences from work and school and increased GP and hospital visits, contributing both directly and indirectly to the overall economic cost of asthma [27].

The potential for both over and underdiagnoses of asthma discussed above, led, in 2013, NICE to the development of "objective" criteria for asthma diagnosis [28]. To date, these criteria are not yet in routine use across the UK, and in the absence of a standardised diagnostic tool for asthma, doctors in primary care continue to diagnose bronchial asthma as always, using clinical symptoms and response to therapy. These issues are even more pronounced in younger children (under 6 years of age), where wheeze is common - occurring in up to a third of children of pre-school age [29]. In this age group, data from the Tucson (US) longitudinal study [30], which reported that preschool wheeze for the majority of children was not associated with atopy – and most children were asymptomatic by school age was one of the first evidence that the mechanisms for wheeze in the majority of children in this age group is was not necessarily the same in all children and adults. A further layer of complexity when attempting to obtain an accurate overview on the state of paediatric asthma is the potential variations in clinicians' use of the 'asthma' label. For example, Speight *et al* recruited a sample of 179 children aged seven years old, who had suffered at least one episode of wheeze in the previous twelve months. They found that 165 had visited their doctor for chest symptoms, however a diagnosis of asthma was given to just 21 children. This was despite 56 children experiencing between 4 and 12 episodes of wheeze in a year, and 31 children experiencing more than 12 episodes of wheeze in a year [31]. Conversely, in a study done in Australia, of 100 children with chronic cough, almost half were given a diagnosis of asthma, without any diagnostic testing. Following investigation, diagnoses of asthma fell to 5% [32]. Similarly, in a population of 90 adults from a tertiary care centre in Canada, 62% were receiving treatment for asthma, despite not meeting the criteria for the condition [33]. Indeed, in a recent editorial, Bush and Fleming, 2016, suggested that over-diagnosing asthma in the general paediatric population is both prevalent and has serious consequences. First, children diagnosed with asthma will often be prescribed treatment including inhaled corticosteroids (ICS) with its (rare) risk of adrenal suppression and osteoporosis, unnecessarily [34]. Second, some healthcare professionals over-diagnosing asthma has the potential for the condition to be regarded as 'trivial',

leading to complacency in those with actual asthma and an increased risk of major adverse outcomes [35].

In summary, paediatric asthma prevalence and burden in the UK is a complex construct - depending in part on how, and in which populations, data are generated. However, there is no doubt that more data are needed in unselected populations. It may well be that potentially "unbiased" recruitment sites such as schools, to obtain these data will offer new insights into the key questions about how controlled children are who have a diagnosis of asthma, and issues related to both over and underdiagnoses.

2.2.2 Asthma Mortality

According to the World Health Organisation (WHO), there have been an estimated 250,000 deaths worldwide attributable to asthma [36], and mortality is continuing to rise, despite advances in treatment and management of asthma in recent years. There are large geographical differences in mortality rates, with higher numbers of asthma-related deaths typically observed in lower and middle-income countries. A probable explanation for this includes the restricted access to healthcare facilities and medication in these areas [36]. In support of this, age-standardised data of asthma-related deaths among 5-34 year olds around the world, recorded between 2001 and 2010, found that asthma mortality was highest in low-income countries, such as South Africa, where an estimated 31 fatalities per million were recorded. This compared unfavourably with high-income countries, where mortality rates for all nations in this category were less than five fatalities per million. Two countries which fell within the group of high-income countries, namely Iceland and Cyprus, recorded no deaths from asthma during the given time period [37].

Due to improvements in asthma, especially the introduction of ICS treatment, asthma deaths have declined since the 1980s [17]. More recent mortality estimates are less clear [38], although Ebmeier *et al* reported a 57% decline in asthma related deaths from 46 countries, of which 78% were high-income and 22% were middle-income, between 1993 and 2012 [38]. However, between 2006 and 2012, the average numbers of deaths per 100,000 has remained stable at 0.19 (0.16-0.21) across all participating countries. According to these data, England and Wales reported the highest number of deaths across Western Europe (0.19 per 100,000) in 2011. This is

compared with Sweden, with no deaths were reported [38]. It is unclear why deaths from asthma are disproportionally high in the UK, but one potential explanation is the higher prevalence of poorly controlled asthma, compared with elsewhere in Europe (of note, not all of the data were available for all of the countries from 1993, the year reported by Ebmeier *et al* [38]).

Clearly differences in asthma-related morbidity and mortality between countries may, at least in part, reflect variations in asthma prevalence – i.e. the more prevalent a condition is, the greater the number of patients who will be at risk of severe outcomes leading to hospitalisations and death. But, for the UK this is cannot be the only explanation, since deaths from paediatric asthma are disproportionally high – even after adjusting for asthma prevalence. For example, Ingrid Wolfe *et al*, 2013 [39] found that death rates across Western Europe from asthma varied from 0 to 1.76 deaths from asthma per 100,000, with the UK reporting 0.66 deaths per 100,000.

In light of the disproportionately high rates of asthma-related deaths in the UK, asthma mortality has been more closely studied in the UK in recent years, through both confidential enquiries and case control studies. For example, a recent large scale national report by Levy *et al*, 2014, examined in detail a sample of 195 UK patients with asthma, whose cause of death was classified as 'asthma', for the period 2012 to 2013. Compatible with previously reported statistics, Levy's report found that the majority of the asthma-related deaths in the UK were adults. Even so, children and adolescents aged twenty years and younger accounted for 14% of the deaths during the review period [14]. The major finding of Levy's report were that deaths were associated with potential avoidable factors, including non-adherence with asthma medications, non-adherence with medical advice, the absence of an asthma action plan, failure to obtain medical assistance during the final exacerbation and overexposure to allergens and tobacco smoke, were all key contributors to the deaths. Additional confidential enquiries, conducted in the East of England between 2001 and 2006, reported that almost half of the deaths from asthma occurred in children who were being treated for mild to moderate forms of the disease [40]. One (of many) explanation for these deaths is that the true severity of the disease was not realised by managing clinicians. Overall, these reviews demonstrate the seriousness of addressing avoidable risk factors, such as non-adherence with ICS, and indicates a poor understanding among patients of asthma management and medication adherence. Environmental factors, including outdoor allergens and

overexposure to tobacco smoke should also not be overlooked since these also increase the risk of death from asthma [41]. Examples of the importance of the environment in asthma control is that, following the introduction of the smoke-free legislation in the UK in 2006, hospital admissions for paediatric asthma reduced by 6802 over the first three years of the ban [42]. Additional factors associated with asthma-related deaths include delays in obtaining medical assistance during an asthma attack. For example, the National Review of Asthma Deaths found that 45% of patients who died due to their asthma did so before seeking medical assistance for their symptoms [14]. On this background, there is increasing need to identify the 'high risk' patient.

Patients who are identified as characteristically at high-risk of an asthma death typically fall into one of the categories below [2]:

- A history of a near-fatal asthma attack
- Unplanned hospitalisations or emergency department visits within the previous twelve months
- Current, or recent, use of oral corticosteroids
- No current use of inhaled corticosteroids
- Overuse of SABA
- Poor adherence with asthma medications
- Food allergies

Some items in this list (e.g. poor adherence) strongly suggest that one way of reducing risk is improving the capacity of children and young people to self-manage their disease. Self-management involves the patient taking responsibility for their own condition and well-being, by working with their doctor to maintain good control of their symptoms, away from the clinical environment. Since the 1990s, self-management plans have become an essential part of treatment for asthma [43]. In many cases, complying with prescribed treatment plans is key to reducing the risk of an asthma exacerbation or fatality, and continued self-management and surveillance is required to ensure that mortality rates continue to fall until they reach near zero. Although personalised management plans have been introduced to try and achieve this, through

documenting treatment plans and individual triggers, the use of these plans in the UK remains low. The national review of asthma deaths found that just 23% of the patients who had died had been given an asthma action plan, and this finding has been echoed across Canada [44], America [45], Australia [46], and Europe [47]. Issues related to self-management are discussed in more detail in section 2.3.1.

Another potentially addressable finding within the concept of self-management highlighted by the National Review of Asthma Deaths is that just under half of the patients who died from asthma did not request emergency help during the final attack [14]. It has been suggested by Levy *et al* 2015 that while this may be due to an inability to request assistance during the final attack, it is equally possible that medical assistance was not requested due to patients being unaware of the severity of their symptoms [48]. This phenomenon may also imply that some patients have developed a higher threshold for coping with asthma symptoms, beyond that considered acceptable by a clinician.

In summary, like asthma prevalence, assessing the burden and preventable factors associated with severe asthma outcomes, including death, is a complex process. However, a consistent theme emerging from individual case reviews of deaths in children and young people are nonadherence with medication, delays in seeking medical help, and no asthma action plan as contributory factors to avoidable deaths from asthma in children. The importance of self-management in addressing these issues is further discussed in section 2.3.1 below

2.2.3 Economic Impact

The economic impact of asthma is high. It is estimated that asthma treatment and care costs the National Health Service (NHS) up to £1 billion per annum. These costs are accumulated directly, owing to hospital admissions, care and treatment, and indirectly because of a potential loss of earnings through missed days at work or school. In other western countries, the economic impact of asthma ranges between $300 and $1300 per patient per year [17]. As the global prevalence of asthma increases, the associated costs are also continuing to rise. For example, in 2007, the total cost of asthma in America was reportedly $56 billion; a 6% rise from 2002 [45]. Moreover, in Europe, the current total cost of asthma is an estimated €17.7 billion annually [17]. Patients with

severe, or poorly controlled asthma, are responsible for approximately 50% of the total costs of asthma, despite comprising only a small minority of asthma cases. The financial implications associated with asthma are considered to be among the highest of all chronic conditions, due to the strong pressures placed on healthcare services [5], and loss of productivity. As the prevalence of asthma is set to rise even further over the coming years, it is becoming increasingly important to improve asthma control and self-manage the condition away from the healthcare setting, to reduce the associated costs and ease the financial burden currently placed on healthcare systems. One of the largest contributors to the direct cost of asthma is the care administered in the hospital setting. A systematic review by Bahadori *et al* in 2009 noted that the patient care received in hospitals accounts for between 47% and 86% of the overall costs of asthma [5]. However, due to differences in study designs and definitions of costs, the economic evaluation that is reported here is limited. Moreover, the data was collected at different time points across different studies, therefore this may also account for some of the differences seen in the costings. Despite this, the review was first to systematically review the economic burden of asthma across different countries. Age standardised data for asthma-related hospital admissions also highlighted that, in 2011, admission rates for adult asthmatics in the UK were among the highest in Europe, second only to Spain [49]. Age-standardised data from the European Respiratory Society (ERS) has also shown that hospitalisations for asthma are higher for children than adults. The lowest reported figure, seen in Portugal, was 76.56 admissions per 100,000, compared with the highest figure, from Italy, which reported 325.17 admissions per 100,000 children aged 15 years or younger [50]. Hospital admission figures for low and middle income countries are less readily available [20].

In the UK, asthma is a leading cause of hospital admissions among children [51]. Between 2011 and 2012, hospitalisations for asthma in the UK reached approximately 65,000; of which 25,000 (38%) were children aged 14 years or younger [6]. It is widely believed that approximately 75% of hospital admissions for asthma in the UK could be prevented with appropriate management [6]. The high rates of unplanned presentations at hospital emergency departments, and hospitalisations, seen across the UK and Europe, are indicative of increasing incidences of suboptimal asthma control, poor disease management and increased exposure to asthma exacerbation triggers [52]. Loss of productivity, including time spent away from work or school

due to asthma or caring for someone with asthma, is one of the most commonly reported factors associated with the costs of asthma [53], and is thought to account for the largest proportion of the indirect costs of asthma [5]. According to the European Respiratory Society (ERS), in England, 69% of parents with children have reportedly taken time off work to care for their child, and 13% have said to have given up their jobs to provide full-time care for their child with asthma [50]. A cost comparison between paediatric and adult asthma populations found that the total accumulated indirect costs of asthma are higher among children. Moreover, parental days lost from work to care for a poorly child are greater among parents whose child has suboptimal asthma control [54].

Severe and suboptimally controlled asthma cases are responsible for 50% of all direct and indirect costs, despite severe asthma cases representing just 10-20% of all asthma diagnoses [17]. In Italy, for example, the annual cost per patient, stratified by disease severity, has ranged from €720 in patients with intermittent asthma, to €3328, in patients with severe persistent asthma [55]. However, this study compared costs across 16 hospital-based clinics, and differences in data collection methods across the different hospital may account for some of the differences seen in the data. Differences in disease classification may also explain some of the variations in costings. Similarly, severe asthmatics in France recorded an average of six or more days in hospital due to their asthma, compared with no days in hospital for less severe patients [53]. Across Western Europe, 43% of children have lost school days due to their asthma. Although no evidence exists showing the direct decrease in academic achievement due to asthma, time off from school can impact on social development, and is likely to indirectly affect academic attainment.

Some research also suggests that nurse-led approaches are as effective as GP-led approaches in treating asthma and improving outcomes, and are more financially viable [39, 56, 57]. However, while Kamps *et al* [57] did see a 7.2% reduction in healthcare costs following a nurse-led approach, and no significant differences in outcomes between children following a nurse-led or doctor-led approach to treatment, this data came from a small sample of 74 children, and therefore is underpowered to detect a significant change. Currently, there are very few studies that provide a comprehensive cost-effective analysis of alternatives to GP-led approaches, and more research

in this area is required to confirm or deny the hypothesis that nurse-led approaches could be a suitable alternative to ease the financial burden on healthcare settings.

2.3 The importance of targeting asthma control

According to both the World Health Organisation (WHO) and the GINA grouping, people with asthma should expect that successful management of their condition will lead to a good quality of life [58]. GINA, a leading international asthma organisation, suggests that the majority of asthma cases can, and should, be managed away from the clinical environment [59]. GINA has played a key part in developing and disseminating standardised guidelines to try and improve asthma control, which have been implemented worldwide. The GINA guidelines define asthma control as the extent to which people with asthma experience asthma symptoms or exacerbations, and the degree to which the symptoms are improved with treatment [59]. The frequency of asthma symptoms are, in part, a reflection of how well controlled the condition is. The rate at which inhalers are used is also typically considered as an indicator of asthma control. GINA characterises good asthma control (also referred to as optimal asthma control) according to four goals [59]:

1. Minimal or no day and night time symptoms
2. The ability to fully participate in physical activity
3. Normal, or near normal, pulmonary function (based on Forced Expiratory Volume (FEV_1))
4. Minimal side effects from medication and decreased use of β-agonist medication.

Poor asthma control (also referred to as suboptimal asthma control) is typically existent in people who use two or more canisters of SABA, or between 10 and 12 puffs per day on their inhaler. These markers are indicative of an increased risk of suffering a fatal or near-fatal asthma attack. Poorly controlled asthma, particularly in childhood, can elicit high rates of unplanned GP and hospital visits and absences from school [60].

Despite the availability of effective treatment for asthma in developed countries, and national and international guidelines depicting recommendations for good asthma management, poorly controlled asthma is still widespread, particularly among children and adolescents. Indeed, the true "burden" of asthma in any country is a combination of both prevalence (discussed above) and control. Unfortunately, there is also mounting evidence that the goals set out by GINA are not being achieved. For example, the Global Asthma Insights and Reality in Europe (AIRE) survey assessed variations in asthma control and asthma management among 7786 adults and 3153 children with asthma in 29 countries. The authors found that just under 6% of children (one in twenty) met all the criteria defined by GINA [61]. Over half of the participants in the survey also reported experiencing day time symptoms, and over a third reported episodes of night-time awakenings. Unsurprisingly, school absences were also higher than expected in most countries. This survey is one of the largest to date, and is supported by findings from both America and Europe. Despite the large sample size, the findings are limited, as low-income participants are potentially under-reported, as the data was collected by telephone survey, therefore potentially excluding those who do not have a phone. Given that asthma is more prevalent in low income households, it may be that asthma control is in fact worse than the data suggests.

A clue that a major driver of these unacceptable data may be poor adherence is provided by studies of other chronic conditions, for example diabetes. In Europe, for example, it has been reported that just 28% of patients with diabetes do not achieve good glycaemic control [62], and many others do not adhere to recommended dietary and exercise regimens [63], despite guidelines highlighting the importance of this in maintaining good health outcomes. Indeed, the high number of asthma deaths in the UK (discussed above) would suggest a high prevalence of poor asthma control throughout the UK.

Indeed, the Asthma Insights and Reality in Europe study (AIRE), reported that the UK has a lower proportion of well or completely controlled asthma cases, compared with other European nations. According to this telephone survey, 52.3% of children in the UK were classified as having well or completely controlled asthma, compared with Germany, where 85.7% of children had well or completely controlled asthma [64]. Adherence to medication was also lower in the UK. The

proportion of children using ICS with severe persistent asthma was 23.8% in the UK, approximately 3.5 times lower than Sweden.

In response to the increased morbidity associated with asthma, countries have used evidence-based methodology to develop a set of national guidelines, informed by the GINA recommendations, aimed at improving asthma control. These guidelines, including those introduced by the British Thoracic Society (BTS) and Scottish Intercollegiate Guidelines Network (SIGN) provide recommendations based on current best practice. In accordance with the GINA recommendations, national asthma management guidelines in the UK typically encourage patients to self-manage their asthma, emphasising the importance of asthma management plans and self-management education, supported by a regular review from a doctor [65]. The aims of asthma self-management are to lower the economic costs associated with asthma and improve quality of life for asthma patients. These aims are achieved through achieving and maintaining a long-term control of symptoms, to the point of maintaining normal activity levels, and minimising the risk of future exacerbations [59].

Since measuring and targeting asthma control is of utmost importance, it is vital to use valid and patient friendly tools. There are three tools available to assess asthma control, recognised by the BTS/SIGN guidelines. Each tool is typically supported by airway function tests, including spirometry, peak flow, airway responsiveness, exhaled nitric oxide and eosinophil differential count in induced sputum [16]. The first is the Royal College of Physicians (RCP) 'three questions'. The National Institute for Care and Excellence (NICE) guidelines recommend that these should be asked during an annual asthma review. A response of 'no' to any of the questions is considered to be consistent with well controlled asthma [66]. The three questions include:

1. Have you had difficulty sleeping because of your asthma symptoms (including cough)?
2. Have you had your usual asthma symptoms during the day (cough, wheeze, chest tightness or breathlessness)?
3. Has your asthma interfered with your usual activities (e.g. housework, homework etc)?

One potential problem with the RCP three questions is they act as a prompt to facilitate a further discussion of asthma symptoms, rather than as a diagnostic tool. Furthermore, these three questions are not recommended for use in children [67].

The second tool is the 'Asthma Control Test (ACT'). The potential advantage the ACT has over the RCP's three questions is that it is (i) clinically validated [68] and (ii) there is a paediatric version for use in younger children. The ACT is also widely used in different countries, and may be considered a global standardised measure of asthma control. The ACT™ is a five-item, patient administered survey, which measures a four-week history of day and night-time symptoms, use of medication and daily functioning. Respondents are also asked to rate their own control over a four-week period. Each question includes a five-point Likert scale of responses, which are calculated to produce an overall score. The scores range from a minimum of five to a maximum of 25. Scores equal to 19 or less indicate suboptimal (poor) asthma control; scores of 20 and above indicate optimal (good) asthma control. This reflects the cut-off with the best sensitivity and specificity for predicting asthma control [68] and is also associated with an increased risk of urgent healthcare use for asthma over a subsequent six months (adjusted odds ratio (OR); 2.29 (95% CI 1.45 to 3.62)) [69]. According to a recent ERS taskforce, an ACT score of 19 or less in a child should trigger more intense clinical monitoring [70]. The ACT is validated in children aged 12 years and older; the Childhood Asthma Control Test (CACT) is a validated alternative for use in children aged 4-11 years. The CACT comprises a similar format, with the addition of two questions. The child is encouraged to answer the first four questions themselves; parents/carers typically complete the remaining three questions. A limitation of the ACT is the use of self-reported data, and therefore subject to social desirability bias, where people completing the tool may wish to be perceived a certain way and therefore amend their answers accordingly, rather than reflecting their true opinions. There is also no differentiation between those toward the middle end of the scale (e.g. scores of 18) and those towards the end of the scale (e.g. scores of 6), despite clear differences in asthma symptoms and daily functioning.

The third tool used to measure asthma control is the 'mini Asthma Quality of Life Questionnaire (AQLQ)', developed in response to the original 32-item AQLQ. The mini version includes 15 questions across four domains, including symptoms, activity limitation, emotional function and

environmental stimuli [71]. Unlike the ACT, each question refers to the previous two weeks and responses are scored on a seven-point scale from one (severe impairment) to seven (no impairment). Similar to the ACT and the CACT, the mini AQLQ has good reliability and cross-sectional and longitudinal validity [72]. The paediatric version (PAQLQ) has 13 questions and covers the same domains as the adult AQLQ, however the paediatric version is currently not validated.

All three tools are self-report measures, and, apart from social desirability bias (described above), incorrect information may therefore be given because the patient may be unable to accurately recall their asthma symptoms over an extended period.

One 'by product' of the use of validated tools to assess asthma control is that they offer a way of comparing what the patients (including children, and/or guardians) think about their own asthma control with what level of control should actually be achieved. Indeed, as discussed, the Levy survey suggests there is evidence that a high degree of discrepancy exists between perceived levels of asthma control and actual levels of asthma control, with many patients regularly over-estimating how well controlled their asthma is. Additional evidence for this phenomenon is provide by the 2006 European National Health and Well-being Survey (NHWS) was conducted on 37476 adults and young people across France, Germany, Italy, Spain and the UK, of whom, 2337 people (<18 years of age) had doctor-diagnosed asthma. When asked to rate their own control on the ACT, 35.3% of people believed that their asthma was poorly controlled. According to the ACT, however, poorly controlled asthma was apparent in half of the participants (50.4%) [73]. Underreporting of asthma symptoms in this way could explain some of the reasons for under-treatment of asthma, and indicates that some people may be either unaware of the characteristics of good asthma control, or their threshold for experiencing asthma symptoms is higher.

To date, data on assessment of asthma control, and discordance in perceived control and actual control, in UK children is limited, and only one community study to date has been reported, using the CACT [74]. In this study, Carroll *et al*, 2012, administered the CACT by telephone to the families of 1284 asthmatic children aged 8-15 years, including 200 children from the UK. Overall, 40% of the children had either parent-reported or self-reported poor asthma control, according to

the CACT guidelines. However, the tools used to assess asthma control are usually supported by airway function tests, and as this data was collected over the telephone, the findings are solely dependent on accurate self-reported data. Moreover, as this was an international survey, there may be cultural or geographical differences that could explain some of the findings. Finally, the sample included children up to 15 years old, despite the CACT only being validated in children up to 11 years of age. There are currently no studies in the UK which have assessed asthma control in schools, using the ACT. Two UK-based studies have recruited school children with asthma, however both studies were conducted in primary schools and neither study assessed asthma control [75, 76].

2.3.1 Self-Management

The GINA guideline recommends that, to achieve effective asthma control, the patient and doctor must work together, from the point of diagnosis, to encourage the patient to self-manage their condition, and reduce the risk of future attacks [2]. As mentioned above, self-management, now considered an important part of asthma management [77]. It involves the patient becoming independent and taking responsibility for the management of their asthma, which includes managing symptoms and using their medication according to their treatment plan, and making lifestyle changes necessary for this long-term condition [78]. Self-management programs emphasise and encourage the development of a relationship between the doctor and the patient. The primary aims of most self-management programs are to increase knowledge and improve control of symptoms [79], as well as reduce rates of medical care. These outcomes are facilitated by behaviours including improved medication adherence. Reviews of self-management in asthma have shown that self-management can be successful in improving health outcomes for both children and adults [80, 81]. There are several interlinked components to consider when addressing effective self-management:

First, patients must have an understanding of the fundamental features of asthma, including changes in breathing, triggers, symptoms, evaluating asthma severity, and knowledge of how to reduce the risk of a future asthma attack [79]. An understanding of medication, and why it is important, is also key to promoting successful self-management. Improving knowledge alone is

not enough to facilitate self-management behaviours and improve asthma control. Instead, people with asthma must make a conscious effort to adhere to their personalised asthma action plan and avoid known asthma triggers, to achieve good control of their symptoms [82]. A review by Coffman *et al* 2009 of self-management programmes, usually implemented as Randomised Controlled Trials (RCTs), showed consistent improvements in these areas [83]. However, usual care was not defined in all of the studies that were included in the review, therefore it is not clear whether children in the control groups were exposed to any other form of education. Second, the number of children with moderate or severe asthma is limited in the sample, therefore it is unclear whether the findings would also be seen in children with more severe asthma. Finally, some of the studies that were included in the review included a small sample size, thus were underpowered to detect a change. Behavioural experts have also recommended that self-management interventions should be grounded in a theoretical framework of behaviour change, which was not included in the review by Coffman *et al.* The use of theory in school-based interventions will be discussed further in the systematic review in chapter five.

Second, patients may not feel confident enough to manage their condition independently, however, as asthma sufferers become more familiar with how to self-manage their asthma, and as the time since their last attack increases, their confidence in their own abilities is also likely to rise. In support of this, Brown *et al* 2014 suggested that, among parents of children with asthma, self-efficacy (that is, confidence in one's own ability to perform a given behaviour) is higher for tasks that are carried out routinely, such as taking regular medication, and is lower for tasks that are less frequent or more complex, such as recognising the symptoms of asthma and managing asthma attacks [84]. However, this study discussed self-report data only, and did not consider parental education and language proficiency, which may influence self-efficacy. However, although knowledge is associated with improved self-efficacy, there is evidence that no relationship exists between self-efficacy and level of education, suggesting that knowledge is related to personal experience, rather than educational attainment [85]. There is also some evidence that cognitive variables, such as attitudes, knowledge and self-efficacy, are associated with improved quality of life among people with asthma, and are lower among those who have visited the hospital emergency department in the previous three months [85].

Third, adolescence is a particularly challenging age group for encouraging self-management behaviours, due to a desire to fit in with peers, and conform to social norms. Teenagers also typically strive to obtain full independence from their parents during adolescence. As children and young people become teenagers, parental involvement in their asthma management is often reduced, and the child assumes more responsibility. However, feelings of embarrassment and concerns about social norms can often lead to poor medication adherence in this age group. Unsurprisingly, Rhee *et al* 2009 also found that higher self-efficacy is associated with lower perceived barriers to asthma self-management in teenagers [86].

Fourth, education is an important component of asthma self-management, and teaches patients about asthma itself, as well as about the skills and motivation needed to independently manage their disease. There is a wealth of evidence to date, which supports the role of self-management education in improving clinical outcomes, although the impact of knowledge on health outcomes is limited. A comprehensive ten year programme, implemented in Finland, between 1994 and 2004, aimed to reduce the societal burden of asthma, through improved doctor-patient relationships and self-management techniques. The premise of the programme was to use new knowledge, particularly in primary care, to diagnose and treat asthma early. People with asthma were educated to self-manage their condition, and be proactive in preventing asthma attacks. Since the programme was implemented, mortality rates, number of days in hospital due to asthma, and disability due to asthma has fallen 70-90%, between 1994 and 2004 [87]. Despite some limitations to this programme, including a lack of a rigorous evaluation right from the beginning, the success of this programme offers a compelling argument for the effectiveness of asthma self-management strategies, in reducing the burden of asthma.

An important component of the Finland programme was the inclusion of a multidisciplinary team in managing asthma from the point of diagnosis, to ensure continuity throughout the treatment pathway. This included a collaboration between asthma doctors and nurses and community services, including pharmacists. The programme also emphasised the importance of written asthma action plans in self-management, and the role of asthma nurses in routine follow-up appointments. The GINA guidelines recommend that a written asthma action plan should be implemented for all patients diagnosed with asthma [77]. Written asthma action plans help

patients and their caregivers to recognise the early stages of an asthma attack, and familiarise themselves with their individual triggers and medication plans. Asthma action plans are best devised during the initial consultation with the doctor, to support the development of the doctor-patient collaboration, which is key to self-management, and to help the patient fully understand their treatment plans and management processes involved in their asthma care. Despite evidence showing that action plans can improve medication adherence and other health outcomes [88], they are often not implemented in practice, even with recommendations in national and international guidelines [89, 90]. The national review of asthma deaths found that, of the 20 children who died in the UK due to their asthma, as few as 30% had an asthma management plan recorded [40]. A second study found that, in a stratified group of 785 adults and children with asthma, just 3% had reportedly been given an asthma action plan [90, 91].

Despite the evidence supporting the benefits of self-management, many people do not possess the skills or motivation to perform health improving behaviours, and doctors often do not have the time to support their patients effectively in this area, particularly in primary care. In recent years, digital technologies, such as smartphone apps, have been developed as tools to support successful self-management. One example of this is a device attached to an inhaler that monitors inhaler use and triggers alerts on a smartphone when it is time to take medication. A recent review of technology in chronic conditions, by Morrison *et al* 2016, concluded that technology does have the potential to support active self-management, through passive self-monitoring, although the research into digital health is still new [92]. A potential limitation of digital health is that it relies heavily on people having access to a smartphone or device, which may exclude some people from lower-income populations. It may also exclude some younger children and teenagers.

The delivery of self-management sills is not necessarily limited to clinical settings. Indeed, school-based self-management education programs have been of particular interest to researchers in recent years, and UK policy-makers also recommend that combining health and educational services is an important aspect of improving quality of life for children with long-term conditions. The integration of these services can also reduce discrepancies in outcomes such as school attendance, which continues to be a key contributing factor to the rising costs of healthcare [5,

93]. The school holds a unique advantage for delivering education interventions for two main reasons:

- Children are familiar with receiving instruction in this environment.
- The school can identify large numbers of children with asthma in a single location, regardless of asthma severity, ethnicity or social deprivation [83, 94, 95]. This also includes children who are 'hard to reach', including those who either do not regularly attend appointments with their doctor, and those who do not have a usual source of care.
- The school location removes the potential bias of parental or clinician input.

To date, there is some evidence detailing the effectiveness of child-centred asthma self-management education, delivered in schools, in improving asthma knowledge, self-efficacy and self-management behaviours, however the evidence for outcomes such as experience of day and night-time symptoms is less consistent [83]. This is further discussed in the systematic review in chapter five of this thesis.

Despite the benefits of self-management strategies, a number of barriers to self-management also exist and need careful consideration. The main barrier to successful self-management is finding a model that fully engages the patient [96]. Given the complexity of managing many long-term conditions, it is difficult to develop a single strategy that will work for all people. This is particularly true for school-age children, as the gap between five and 18 is broad, and spans a number of developmental stages. Therefore, it is important to acknowledge that not all self-management techniques will work for all people. To overcome this, interventions can focus on commonly reported gaps in knowledge, including the basic pathophysiology of asthma, or the role of medication in treating the condition. Gaps in knowledge are explored further in the focus groups, discussed in chapter four. Some people will also find the concept of self-management daunting, and will be overwhelmed at the prospect of taking responsibility for managing their asthma. This further highlights the importance of a strong doctor-patient partnership and an asthma action plan, which will detail the symptoms, triggers, and management plan.

2.4 Medication Adherence

The aim of asthma management is to decrease the levels of asthma morbidity and mortality by achieving good control of asthma symptoms [2]. According to the WHO, adherence to prescribed medication is defined as "the degree to which the use of medication by a patient corresponds with the prescribed regimen" [97]. There are no specific guidelines detailing what constitutes non-adherence, however it is generally applied to instances where less than 80% of medication is taken as prescribed [10]. The WHO has reported that approximately 50% of people in developed countries do not take medication as prescribed, across a range of long-term conditions [98]. There are further reports that more than 50% of children with asthma do not adhere to their treatment plans [9]. Good adherence to asthma medication is difficult to maintain for several reasons, including social factors, poor understanding of different medication, the role of the parents, and the transition between childhood and adolescence. Adherence to asthma medication has been found to be lower than other conditions, such as oncological diseases, possibly as concerns regarding asthma medication (e.g. ICS) may outweigh the beliefs about the necessity of the treatment. Poor adherence is also seen in people with less severe asthma, suggesting that some people underestimate the seriousness of asthma, and the implications of ignoring medication [9]. The clinical implications of poor adherence to asthma medication include increased levels of hospitalisations and poorer asthma control [9]. Heaney and Horne have suggested that, in patients with difficult to control asthma, a reduction in hospital admissions could save the NHS up to £43 million [99]. Poor adherence is also linked to an increase in the risk of an asthma attack and, in severe cases, death. Sporadic use of asthma medication can also reduce the effectiveness of the medication.

Global rates of non-adherence with asthma therapies typically range from 30-70%; and there are large variations between countries. In developed countries, for example, adherence with preventive medication has reportedly been seen to fall as low as 28% [98, 100], and adherence in the UK is generally lower than other European countries. According to the Global Asthma Physician and Patient survey, 24% of adults in the UK took their asthma medication as prescribed, compared with 48% of adults in other European countries [101]. Vermeire *et al* 2002 also found

that ICS use among children with severe asthma in the UK was 23.8%, compared with Sweden, where 83.3% of people with severe asthma were using ICS [64]. Of course, adherence may be measured differently in different countries, and each country may have their own standards of what constitutes nonadherence, therefore it could be that geographical differences explain some of the variances in these findings. Global comparisons of adherence among teenagers remains relatively scarce, however Desai and Oppenheimer 2011 suggest that adherence is lower among children living in an urban minority community [102]. Reasons for this may include increased exposure to environmental allergens, such as dust and cockroaches, as well as potentially higher levels of stress in these areas. While variation in adherence does exist between countries, knowledge of what predicts nonadherence is low. Some variables, such as household income, have been thought to act as a predictor, with lower socioeconomic status (SES) being associated with poorer adherence [103]; however, barriers to adherence are believed to encompass a range of explanations, which will be discussed further.

Adherence to asthma medication is a complex issue, and one that is the focus of many self-management interventions. To improve rates of nonadherence, researchers and healthcare professionals alike must first understand the barriers to adherence. Horne 2006 has previously suggested that there are two types of nonadherence: intentional and unintentional [9]. Intentional nonadherence refers to the patient making a conscious decision not to use their medication; unintentional nonadherence refers to factors that are outside of the patients' awareness or control, for example poor inhaler technique. Furthermore, the most widely reported reasons for nonadherence with asthma medication (e.g. incorrect inhaler technique or forgetfulness) can be further understood by considering three main categories: (1) poor understanding; (2) social factors; (3) structural factors. Table one displays the most commonly reported barriers to adherence, according to these three categories.

Barrier to Adherence	Category
Intentional Nonadherence	
Side-effects of medication	Poor understanding
Incorrect beliefs about medication	Poor understanding
Social Stigma	Social
Unintentional Nonadherence	
Inhaler technique	Poor understanding
Complicated treatment plans	Poor understanding
Forgetfulness	Poor understanding
Difficulties obtaining a new prescription	Structural
Parental Roles	Social

Table 1. Categorical barriers to adherence

As seen in table one, poor understanding of asthma medication explains a large proportion of the reasons for both intentional and unintentional nonadherence. Social and structural factors, however, are also important to consider, especially when thinking about adherence in children and young people.

Side-Effects

The side-effects of asthma medication can be unpleasant, as expressed by up to one third of asthma patients studied [9]. The use of steroids in treating asthma is also concerning for many people, due to the stigma surrounding steroids, and known alternative uses. While this apprehension strongly emphasises the importance of a good doctor-patient relationship, most of the side-effects are discussed with patients when their medication is prescribed, however it could be twelve months before patients attend a review with their doctor, and concerns about side-effects may only develop once the treatment has started. Other side effects of the medication include an unpleasant taste, and feelings of nausea. Although the role of medication, and potential side effects, are discussed during the consultation, the unpleasant side effects may act as a stronger predictor of adherence behaviour, rather than a desire to control the symptoms, especially if the patient is feeling well.

Incorrect Beliefs

Unlike reliever inhalers, where the effects of the medication are immediate, controller medication requires long-term use, to benefit from the results. Subsequently, some people with asthma fail to acknowledge the importance of their controller medication, as they cannot see an immediate benefit. Controller therapy may also be taken incorrectly in response to asthma symptoms, if people do not understand the differences between inhalers. Similarly, some people with asthma

may stop using their inhalers if they are feeling well and do not experience any asthma symptoms. In some cases, it may be that they are outgrowing their asthma, and therefore need to step-down their medication; however, in other cases, it could be that some people do not understand the role of their controller medication in reducing the symptoms of asthma [104]. Conversely, beliefs regarding the efficacy of an inhaler can be reduced if asthma sufferers continue to experience asthma symptoms, despite using their medication correctly. Instead of speaking to their doctor to discuss a possible stepping-up of their treatment, some people may stop using their medication and become 'used' to living with the symptoms, thus developing a higher threshold for experiencing asthma symptoms.

Social Factors

Social concerns, for example bullying, is a common barrier among teenagers and young people. Adherence to children and young people often falls below 50%, regardless of the level of severity [105]. Adherence is also reportedly lower among older adolescents, compared with younger children [102]. Among many adolescents, it is important for them to achieve a good social standing among their peers, and many may be reluctant to actively avoid asthma triggers, for example pets, or use an inhaler in front of their friends [106], due to an unwillingness to deviate from social norms. Similarly, feeling reliant on medication can reduce their independence [107], and may prompt feelings of weakness or embarrassment for seeming different to their friends. In support of this, focus groups conducted in Ohio with 24 asthmatic children revealed that a teenagers' desire to be 'normal' and fit in with their social group often outweighed their opinions regarding the potentially serious consequences of improper asthma management [107]. The findings from Velsor-Friedrich *et al* [107] also highlighted some valuable insights into how best to manage asthma in teenagers. However, given the qualitative nature of the study, the findings are open to interpretation, and must be treated with caution. It is unclear from the methods that are reported how many researchers were involved in the analysis of the transcripts, and whether or not data saturation was reached. Moreover, it is unclear whether the researchers had a framework in mind, prior to collecting the data and conducting the analysis. Therefore, it is

difficult to know whether the conversation within the focus groups was directed towards certain topics.

Incorrect Inhaler Technique

Incorrect inhaler technique is common among people with asthma, and can explain reasons for poor asthma control [108]. Although unintentional, mistakes in inhaler technique can mean that patients are not inhaling the correct dosage of medication into their lungs [109]. Although spacers are used to counter this, they are often not used as intended, particularly among teenagers, as they can be bulky to carry and are not discrete when being used. A systematic review of inhaler technique and patient adherence demonstrated that education programs improved adherence as well as inhaler technique [110].

Complex Treatment Plans

The complex nature of asthma treatment plans has also been identified as a barrier to adherence. In some cases, people with asthma have multiple inhalers for their asthma, which need to be taken at different times for different reasons. For example, prescribed controller medication (also referred to as "preventer inhalers" in this thesis) needs to be taken twice a day, morning and evening. Not only can this be difficult to remember, particularly when distracted by other tasks, such as getting ready for school or homework, but it also places a significant amount of responsibility on patients and their families [111], which, as discussed earlier, can act as a barrier to self-management. To support this, Cramer *et al* 1989 identified that lower rates of adherence when the number of doses per day were higher [112]. Although this was seen in a sample of patients with epilepsy, Bender 2002 agreed that people with asthma are also more likely to adhere to a treatment plan that is simple to understand and implement [113]. In addition to controller therapies, people with asthma will also have a reliever inhaler, for use only when the symptoms of asthma appear. Some people may be unaware of the differences between the different medications, and therefore may be using their inhalers incorrectly. It could also be that some people fail to understand the need for multiple medications, and believe that they are fine to treat their asthma using a single inhaler.

Forgetfulness

Forgetfulness is a common barrier to adherence across a range of chronic conditions. Among teenagers and young people with asthma, forgetting to take medication has been widely recorded due to homework, extracurricular activities and getting ready for school [114]. Forgetfulness is also common among adults, and a study by Rand in 2005 [115] noted that adult patients forgot almost half of the information given to them by their doctor, which may include their prescription plan and how to use their medication correctly.

New Prescriptions

Difficulties in obtaining a new prescription, due to both structural and financial factors, can contribute towards unintentional nonadherence. It has previously been reported that people from lower SES households often have lower levels of adherence to asthma medication [116]. One reason for this could be due to a lack of access to primary or tertiary asthma care [117], particularly in countries where healthcare is privatised. Some parents have reported that the financial cost of treatment for asthma has previously prevented them from obtaining the correct prescription for their child [118]. Difficulties in obtaining a new prescription when an inhaler either expires or needs refilling can be costly, and time-consuming to collect, which can reduce one's desire to renew the prescription [113]. It could be, for example, that some people will not use their controller medication every day to make it go further, or will avoid using their reliever inhaler when they need it to ensure they do not run out quickly.

Family

The final barrier to adherence is parental factors, including the role of the parent in managing asthma in children and young people. As previously mentioned, adherence to medication is lower among older adolescents, compared with young children. As children and young people enter a transitional period of adolescence, they classically want to seek independence from their parents/carers. McQuaid *et al* 2003 have suggested that as parents begin to reduce their input into their child's asthma management, children and teenagers may not automatically resume responsibility [111]. To overcome this, it may be that, although parents/carers generally have overall responsibility for their child's asthma during their younger years, children should be

involved in their disease management from an early age, so that as they reach adolescence and their maturity develops, they have the skills necessary to conceptually understand their asthma management strategy, and the propensity to remember to take their medication regularly. This is supported by the suggestion by McQuaid *et al* that adherence to medication is dependent, in part, on how well one understands asthma and the concept of prevention [111]. Further, although many adolescents will assume responsibility for their asthma, their adherence is still largely influenced by parental factors and the home environment. For example, if there is a lack of routine within the household, and taking their medication was never part of a structured routine growing up, it can be easier for teenagers to forget their medication, particularly in the absence of any symptoms. It is also important to consider how parental beliefs towards asthma medication can be echoed by children during adolescence. Consistent with the literature on adult medication adherence [119], parents who have stronger beliefs about the effectiveness of their child's medication generally have higher levels of adherence, compared to parents who have strong concerns about the negative effects of treatment [120]. However, the evidence for this comes from a parent-reported study, therefore the data may be biased by the parents wanting to be perceived a certain way. There is also no qualitative data to subjectively support the findings.

Following the noted barriers to adherence, there has been a movement towards improving adherence, through electronic monitoring. For example, smart inhaler devices are designed to record when patients are using their asthma inhalers, by keeping a log of the date and time, which is recorded automatically using a smart phone. Other electronic monitoring devices have also included a daily text message, to remind people to take their medication. Although these methods have seen increases in medication use [10], and there is evidence that electronic monitoring is also effective in increasing adherence in other chronic conditions, such as diabetes [121], there is no guarantee that the patient is using their inhaler correctly, or indeed at all, as the device will only measure that the inhaler has been used, not whether the patient inhaled any medication directly. There is also evidence that the impact of such methods is short lived, and subsequently drops once the reminder has been removed [122]. Electronic monitoring and reminders are also only suitable for those who have a smart phone or device, which may exclude certain population groups, such as younger children and those from low SES households.

Many of the barriers that have been discussed here point to a poor understanding among patients of how to effectively manage their asthma at home. These barriers also highlight the importance of a strong doctor-patient relationship, which is also key to effective self-management. Effective consultations enable the patient to consolidate their understanding, and make an informed decision about their condition. Conversely, people who do not have a good relationship with their doctor can feel dissatisfied, or are more likely to forget or misunderstand what they have been told [123].

2.4.1 Knowledge

To date, there is a limited understanding of why difficulties in asthma management occur, and how to overcome them [124]. It has long been suggested, primarily by behavioural psychologists and social theorists, that knowledge, attitudes and beliefs are key determinants of health behaviour, and there are several models, such as the Theory of Planned Behaviour and the Health Belief Model, that support this concept. It is also widely accepted that knowledge is a prerequisite for reaching effective asthma management [125]. More recently, researchers have sought to better understand the role of knowledge in asthma management. Despite expectations that increased knowledge improves asthma management, the evidence to support this is conflicting. Some literature reports that knowledge has no effect on health outcomes [111, 126, 127], and other research has indeed demonstrated a relationship [124, 128, 129].

To date, no standardised measure of knowledge exists, and no single assessment tool has received widespread acceptance and validity. Therefore, it is difficult to quantify and compare the outcomes of different studies, due to inconsistencies in the way in which knowledge data is collected.

Knowledge of asthma varies widely and, as expected, knowledge is typically higher in older teenagers and adults [130], although knowledge of asthma is generally low across all age groups [85, 124]. One study by Gibson *et al* found that, not only was knowledge low among high school students with asthma, but it was also low across peers and teachers too [124]. Knowledge on prevention, and treatment for exercise-induced asthma was found to be particularly low in this study and the authors also found that tolerance towards asthma was moderate (38% of students

believed that students with asthma are embarrassed to use their inhalers in class). It is important that knowledge is addressed in younger age groups, to reduce the potential impact of poor knowledge continuing into adult life. Although these findings do highlight a lack of knowledge among teenagers and teachers with asthma, the findings must be treated carefully. The data was collected from children aged 13-14 years only, and, as secondary school age covers a wide range of developmental ages, their views may not represent those of children lower down the school. There was also a lower response rate for teachers, as the questionnaires were self-administered and were conducted in their own time. Therefore, the teachers who did complete the questionnaire may have had an existing interest in asthma, thus the findings may not be generalizable to the wider teacher population of the school. This study was also conducted in 1995, therefore the findings could arguably be outdated.

A more recent study by Sin *et al*, conducted in 2005, found that, in a sample of 62 African-American people with asthma, although knowledge was seemingly high, according to an asthma knowledge questionnaire (75% correct), 41% of participants did not believe that it was possible to prevent an asthma attack [131]. Sin *et al* also found a significant correlation between knowledge of asthma, social support and self-management behaviours, which supports the findings of Gibson *et al*. This study, however, included a small sample size (n = 62), and participants were recruited via a convenience sampling method. Given the sample was also African-American teenagers, the findings may not be generalizable to teenagers from other ethnic groups.

Conversely, McQuaid *et al* [111] measured children's knowledge of basic asthma facts, using the Asthma Knowledge Questionnaire [132]. Correct scores ranged between 36% and 96%, with an average score of 76% correct. The data also showed that older children knew more about asthma than younger children, however this was not reflected in levels of medication adherence. Similarly, Velsor-Friedrich *et al* assessed asthma management in teenagers, using focus groups, in a sample of 24 teenagers with asthma from 4 high schools in Chicago. In accordance with the barriers to medication adherence that were discussed earlier in this chapter, Velsor-Friedrich *et al* found that although most teenagers in the sample demonstrated knowledge of asthma triggers and basic asthma management, they did not always use their knowledge, due to social factors,

including a fear of being different [107]. These findings indicate that, even where knowledge is seemingly high, a desire to comply with social norms is a bigger driver of behaviour than a desire to self-manage asthma symptoms. Although this does provide evidence surrounding adolescent management of asthma, both studies described here relied solely on opinions from the teenagers themselves, and were not compared with viewpoints from family or friends to validate the social concerns. Second, some elements of the asthma medication plans (for example use of reliever medications) were not assessed, therefore an accurate assessment of adherence could not be conducted.

Gender and educational attainment are also thought to be associated with knowledge, and there is some evidence that increased knowledge is seen in females, as well as in those with a higher level of school education [111, 133]. One study of 29 adults with asthma found that, across all age groups, females had consistently higher levels of knowledge than males, according to the Knowledge, Attitude and Self-Efficacy Asthma questionnaire [133]. Although positive attitudes were also linked to knowledge, no effect was seen on adherence. It is noteworthy, however, that this study had a low sample size, and the response rate was only 59%. Further, within this sample, most of the participants had mild asthma only. Adherence was also assessed using self-report measures, therefore some responses may be subject to social desirability bias.

While knowledge of asthma is generally low, most people with asthma seem to have a basic understanding of the pathophysiology of asthma, including triggers and symptoms. Some of the commonly reported gaps in knowledge include misperceptions about the role of medication, and poor inhaler technique [111], as well as perceptions of asthma control. The National Review of Asthma Deaths previously reported that asthma deaths in children were associated with a poorer perception of control and inadequate awareness of adverse outcomes [14]. The Room to Breathe Survey also noted that parents of asthmatic children can have overly optimistic perceptions of their child's control [74].

Since medication adherence is dependent, in part, on a good understanding of asthma, it is reasonable to consider knowledge when developing interventions to improve asthma management, although it is clearly not sufficient on its own to improve outcomes. It is also important to consider other factors, such as attitudes and peer awareness, as social norms may be

a bigger predictor of behaviour than asthma symptoms, particularly among teenagers. The literature also suggests that, although knowledge of asthma improves with age, this does not always translate into better adherence behaviours, and knowledge of asthma management and prevention remains limited. It is clear that a standardised validated tool for assessing asthma knowledge is required, however reasons for why this has not yet been achieved include differences in sociodemographic characteristics, which are not typically associated with treatment outcomes [125].

Although the evidence for the role of knowledge in improving outcomes for children with asthma is limited, the BTS and SIGN guidelines recommend that asthma consultations should be viewed as an opportunity to reinforce and extend patients' knowledge and skills [16]. The BTS and SIGN guidelines recommend that specific knowledge, in particular being able to list all prescribed medications and their uses, is an important component of self-management, particularly among adolescents. Similar suggestions are also made in the GINA guidelines for global asthma management. Although these guidelines do recognise that improved knowledge does not always lead to improved outcomes, the guidelines highlight the importance of sufficient knowledge, as it can facilitate some self-management behaviours.

In summary, it is evident from the literature that knowledge of asthma is lower than might be expected, which may have an impact on medication adherence and other asthma outcomes. The absence of a standardised tool for assessing knowledge of asthma makes it difficult to compare data from different studies. However, knowledge is important to consider when included as part of a wider intervention, addressing a number of barriers to self-management.

2.5 Asthma Management in Schools

Historically, the home environment has been commonly considered when thinking about interventions to improve asthma management and outcomes away from the clinical environment. However, more recently, the school has become an alternative location to consider, given its familiarity to children and access to large numbers of children with asthma in one location (as discussed earlier in this chapter). Considering this, the Lancet commission recommends a move

towards asthma prevention and cure, rather than a treatment-based approach to management. The rising prevalence of asthma, both in the UK and globally, reflects poor management of the condition. Accordingly, despite the marked variations in asthma prevalence, acute asthma is the most common cause of hospital admissions among children of all ages in Europe [17]. The objectives of asthma management interventions are to enable people living with asthma to better understand asthma, and build their confidence to self-manage their asthma. Self-management is an integral part of asthma management, and requires all stakeholders (patients, carers and physicians) to work together to improve outcomes.

As discussed in Section 2.2.1, asthma can be exacerbated by a range of different triggers, and each person will have a different combination of medications and management plans. Due to this, it can be difficult to develop an intervention that is tailored to the specific needs of each child. Tailored interventions are often implemented outside of the school environment, normally in the home, as they can focus on the individual environment and discuss targeted allergen exposure within the home [134]. However, interventions of this nature can be expensive to run, and may exclude people who live in more rural areas. Although rare, there are also some studies which have implemented self-management interventions in a clinical setting. The benefit of this environment is that it provides direct access to other services, including doctors and nurses, as well as community services such as pharmacies. Many studies to date that have conducted studies within the primary care setting have used a nurse-led model [56, 135], and have seen improvements in unscheduled care, however the findings from Griffiths *et al* [56] were not significant.

As previously discussed, the school environment is an important space for asthma-focused research. The school site, including school policies and school personnel, may be important when thinking about successful management of asthma in schools. It is possible that within the school, there will be staff members (e.g. teachers), or other students, who are unaware that a child has asthma, and will therefore be poorly equipped in identifying and handling worsening asthma symptoms [136]. The school environment varies widely between different countries, however in the UK, particularly in London, it is not unusual to have either a school nurse in some schools, or community nurses taking care of a number of schools within a single borough. It is also notable

that different schools will have different policies for managing asthma, including the storage of medication. A move towards standardised school asthma policies could be an important first step towards achieving improved asthma management within the school environment. Recently, different countries have started developing 'asthma friendly schools', which incorporate common goals to create a knowledgeable and supportive school environment and build a collaborative relationship with local authorities. Such programs currently exist in Canada, America, Australia, and the UK [136]. Central to the asthma friendly schools initiative is identifying all children with asthma in schools, ensuring they have a management plan in place, and a named asthma-responsible member of staff at each school.

In addition to moving towards a supportive school environment, the role of the school nurse, or healthcare provider within the school, is also an important consideration for asthma management. School nurses provide care on a wide spectrum, including direct care, emergency response, and acting as the contact between the school and the guardians, and healthcare services. Despite this, widespread cuts to school nurses have been reported in recent years, due to budget restraints within the education sector. The evidence detailing the role of school nurses in improving outcomes for children in schools is limited, however extant research has highlighted the positive impact of school nurses on immunisation rates, student health records and continued care for children with long-term conditions, including asthma and diabetes [137, 138]. Moreover, a recent study from California showed that school absences for children with asthma declined upon recruitment of a full-time nurse within the school, and fewer emergency department visits were reported by parents [139]. However, this study was not designed to be experimental, therefore the schools were not selected on a randomised basis to be either an experimental or control school, leading to some differences in school characteristics at baseline.

Similarly, a European taskforce, published in 2010 by EAACI/GA^{2}LEN published a document detailing a model of care for allergic children in schools [140]. In addition to the goals discussed within the asthma friendly schools model, this taskforce also recommends that asthma education should be provided for staff members, particularly those identified as responsible for asthma within the school. It was also suggested that asthma should be included within the curriculum, to educate children without asthma about the disease and how to recognise worsening symptoms.

According to the taskforce, the recommendations listed within the taskforce document have been applied in a number of school interventions for children with asthma, which have seen a positive impact across a range of outcomes [140].

In summary, the school environment could act as an important 'third space' for delivering educational self-management interventions aimed at children with asthma. Careful consideration needs to be given however, as there is some variation in the way in which schools operate, both nationally and internationally, and different school policies and healthcare structures (e.g. the presence of a school nurse vs a community nurse) within schools may influence the way in which asthma is managed. However, the school could be a good location for delivering interventions, not just to children with asthma, but also to their peers, in accordance with the recommendations from the 2010 European taskforce.

2.6 Overall conclusion

Figure three displays a summary of the chapter.

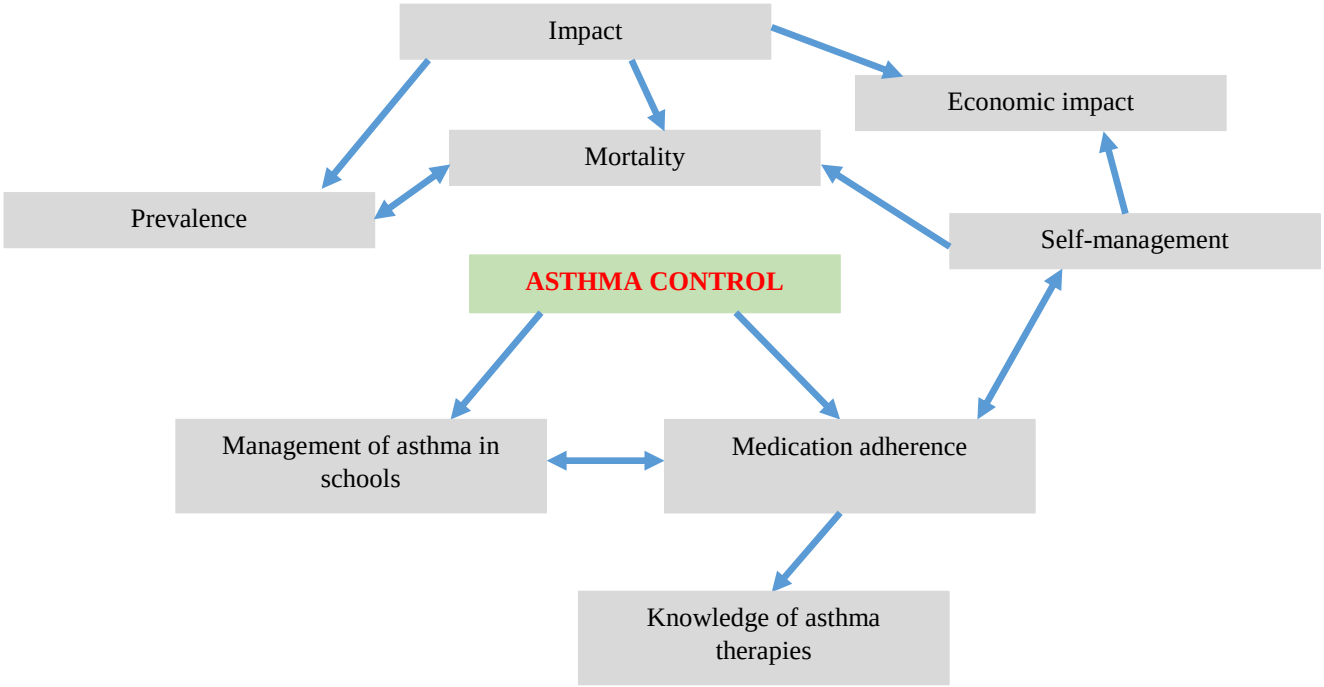


Figure 3. Summary of the chapter

Hospitalisations and deaths from asthma are much higher in the UK, compared with other countries in Europe, however the reason for this is not clear. One reason could be a higher number of people in the UK with poor asthma control, compared with other European countries, however this has not been directly tested. Investigations into deaths from asthma in the UK have noted a number of avoidable factors which have contributed to the death. These factors include the absence of an asthma action plan, and non-adherence with medication and clinical advice. According to the WHO, medication adherence is a problem around the world, and often falls below 50%. Adherence has also been found to be lower in the UK, compared with elsewhere in Europe. Poor adherence with medication for asthma can lead to increases in hospitalisations and poorer asthma control. There is also an increased risk of experiencing an asthma attack among people who do not take their medication correctly.

According to GINA, people with asthma should be able to control it well and engage in a normal active life. However, global trends have shown high rates of poorly controlled asthma, despite recommendations from GINA. In response to this, self-management has become an increasingly important aspect of asthma treatment and care. Self-management encourages the individual to take responsibility for their own health, away from the clinical environment. Good self-management requires people to have a good understanding of their asthma, which may not always be true, and may be a barrier to active self-management. However, it is expected that active self-management could reduce the burden placed on the NHS, by seeing a reduction in unplanned hospital visits.

Despite self-management relying on a good level of knowledge, the literature regarding the impact of knowledge on asthma outcomes is mixed. Some studies have shown improvements across a number of outcomes following an intervention, while other studies have not seen an effect after increasing asthma knowledge. There is currently no standardised measure for assessing knowledge in asthma, which may contribute towards the variation seen in the literature. According to the literature, medication adherence is also problematic, particularly as nonadherence can be either intentional, for example due to a belief that the medication does not work, or unintentional, for example due to incorrect inhaler technique. Such barriers to medication

adherence in asthma should be investigated and addressed, in order to improve asthma control and overall management of the condition. The current gaps in knowledge indicate that greater education is needed surrounding the role of different asthma medications in treating the disease, as well as when to take medication, and how to use inhalers properly. Further gaps in knowledge are seen in people without asthma, who do not have adequate awareness of how to respond during an asthma exacerbation. These gaps can be addressed during an educational intervention, and the school environment could be an effective space for delivering this. The school provides access to large numbers of children with asthma, regardless of severity, SES or ethnicity. This also includes children who do not regularly attend appointments with their GP.

Plain Language Summary

Hospital visits and deaths from asthma are higher among children and young people in the UK than other European countries, however the reason for this is currently unknown. It could be that there are more children and young people in the UK with poor asthma control, however this has not been directly measured. Unplanned visits to medical providers, as well as time spent off work and school, somewhat contributes to the financial pressures currently placed on the NHS, therefore it is important that children and young people, as well as adults with asthma, learn to self-manage their condition at home.

Self-management has become an important component of asthma treatment over the years, however much of the research regarding self-management interventions has been done outside of the UK, mainly in America and Canada. However, evidence from research done in America has shown that self-management interventions can be an effective way to improve asthma control and reduce rates on unscheduled care. Notably though, while knowledge is an important part of these interventions, there is no direct evidence that improving knowledge alone is enough to improve outcomes for people with asthma. Instead, attitudes and beliefs should also be considered.

There are several ways to measure asthma control. These include the ACT, the RCP three questions, and the AQLQ; and each should be used alongside clinical measures, including lung function testing. However, improving asthma control alone may also not be enough to improve outcomes. Medication adherence is also an important part of self-management behaviour. According to the literature, nonadherence can either be intentional, or unintentional. Many of the commonly reported barriers to adherence include forgetfulness, side-effects, incorrect beliefs about medication and social concerns, including embarrassment and a fear of being bullied.

The school has become an important location to consider when designing self-management interventions for children. It provides access to large numbers of children with asthma, regardless of ethnicity or SES. There is also the possibility of delivering an intervention to children in schools without asthma, to raise awareness among peers and address some of the social concerns commonly associated with adherence.

Chapter 3. Assessing the Burden of Disease: School-based Survey

In chapter two, I discussed the evidence for the disproportionally high prevalence of asthma among children in the UK, and concluded that a putative explanation is high prevalence of suboptimal asthma control in UK school children. But to date, has been no assessment of asthma control in London secondary schools, using the ACT. Therefore, in this chapter I describe development of an assessment tool, designed to bridge this gap, as well as the results of a pilot and full-scale trial. Specifically, I report the development and resulting data from an online assessment tool to assess the current burden of disease in a population of London secondary school children with asthma. The first section of this chapter will discuss the development of the questionnaire, including the use of Patient and Public Involvement (PPI) and ethics. I will then discuss the pilot study, followed by the methods and results of the main questionnaire study. This chapter will end with some overall conclusions, based on my findings.

3.1 Development of the questionnaire

3.1.1 Sampling

The target population for this cross-sectional observational study was students with asthma who were attending secondary school in any of the thirty-two London boroughs. A key inclusion criteria was that students must have received a clinical diagnosis of asthma from their doctor and be registered with their school as having asthma. Eligible students were also required to be aged between eleven and eighteen years, since the ACT has only been validated in children twelve years and older [141]. However, my inclusion criteria allowed recruitment of eleven-year olds, as feedback from schools during my pilot study suggested that it would be too challenging to differentiate between students who were eleven and students who were twelve years old on the school register. The final inclusion criteria was that students must be attending the school where they completed the questionnaire. No limits were applied to the type of school that students were recruited from; instead, comprehensive, independent and grammar schools were eligible for participation. All students who met the inclusion criteria were invited to participate, and were recruited over a twelve-month period, from October 2014 to October 2015. A power calculation

was not done; instead all eligible schools in London were invited to participate, and students were recruited using a convenience sampling strategy.

3.1.2 Using Patient and Public Involvement to develop the questionnaire

A key part of the development of the questionnaire was to involve children and young people. According to INVOLVE [142], patient and public involvement (PPI) should include people with experience of living with the condition being studied, as well as people who are representing their loved ones who live with the condition being studied (e.g. caregivers or members of their support network). PPI is important in research for many reasons. First, the views of a 'lay' person can offer a different perspective to academics or clinicians. This includes providing specialist insight into the concerns of the population of interest [143]. Second, the views expressed by patients or members of the public can complement those of the researchers, and further support the aims of the research. However, the views of the patients and public can also challenge those of researchers, and can contribute towards a more focused research question and study design.

In this study (prior to the pilot study), stakeholder engagement was incorporated in several ways. During the development of the questionnaire, testing of the tool was conducted with teenagers with and without asthma. The primary aims of this were to ensure that the website hosting the questionnaire was user-friendly, and to test whether the questions were appropriate for the target age-group, and could be completed in a reasonable timeframe. Initially, four workshops were conducted. The first two were conducted in collaboration with the Centre of the Cell (COTC), and included four young people without asthma in each workshop. The aim of these workshops was to discuss the website design and accessibility, to ensure that it was appropriate for the target cohort. In all, the children felt that the website was appropriate and could be easily navigated by children of all ages within the target age range. The third workshop included 15 young people with asthma aged 13-17 years; the final workshop included 14 children with asthma aged 11-13 years. The focus of these workshops was the content of the questionnaire, to test whether the questions were easy to understand, and were appropriate for the target age group. The feedback from these workshops indicated that the questions should be specific, particularly when asking

about how comfortable students felt when using their inhalers, as inhaler use can vary throughout the day. Following this, the questions were amended to make clear whether inhaler use referred to inside or outside the school environment. The children also recommended free-text answers to be added to some questions about adherence, to enable the students to elaborate on their responses, particularly if they felt that the multiple-choice options did not apply, or more than one was fitting.

In addition to the workshops with children, unstructured consultations were also held with healthcare professionals to discuss the questionnaire. These discussions were held with clinical nurse specialists, paediatricians, psychologists and researchers. The aim of these discussions were to ensure that the questions were capturing clinically appropriate information that was relevant to the research objectives. Stakeholder meetings were also arranged, which were attended by members of the research team, respiratory specialists (including GP's and consultants), school nurses, psychologists and other London-based researchers working on paediatric asthma. During this meeting we discussed the preliminary findings from the pilot study, and how the outcomes could be used to inform further research. Gaps in existing asthma management strategies were also identified, as well as recommendations for how these gaps could be addressed. This was helpful in identifying current clinical concerns, and mapping these concerns to the questionnaire data. Key outcomes from the meeting included ideas for the design of a future schools-based self-management intervention, based on current best practice.

Finally, the preliminary findings from this study were presented at a lay research advisory panel, organised by the PPI lead at the NIHR CLAHRC North Thames. The advisory panel included eleven adult members, many of whom had experience of living with asthma, or caring for someone with asthma. The key points that were raised by panel members included strategies for engaging teenagers in research and identifying barriers to medication adherence among teenagers and how to overcome these. Following the meeting, a report was submitted to the CLAHRC to detail how these points had been addressed.

3.1.3 Ethics

Ethical approval was obtained from the Exeter Research Ethics Committee (REC) on 3rd June 2014 (reference number: 14/SW/0120). Although this study was considered extremely low risk,

both in terms of children's health and potential harm to the students, there were several ethical considerations that were addressed, prior to conducting the pilot study.

First was child protection and safeguarding. At least two members of the research team were present at the schools during each data collection session. Therefore, all researchers obtained a valid Disclosure and Barring Service (DBS) check, prior to entering the schools. All schools were aware of this, and could choose whether this satisfied the child protection policy of the school, or whether further strategies needed to be enforced. One member of school staff was also asked to be present at all times.

Second was the collection of parental consent and student assent. As the students were aged 18 years and younger, written assent could not be collected from the students until their parents had been informed of the research, and their right to withdraw their child. Parent information sheets and withdrawal forms were sent out via the schools two weeks before the scheduled data collection. To maintain data protection, the schools were responsible for disseminating the information sheets to the parents; however the parents were provided with contact details for the research team, should they wish to discuss the research further. During the pilot study, informed opt-in consent was collected from parents' two-weeks prior to the data collection. Recruitment via this method was limited, and feedback from the teachers indicated that this was too difficult to coordinate, on top of their existing workload, and many schools cited this as a reason for withdrawing from the study. Following the pilot study, an amendment was submitted to the REC requesting the use of opt-out parental consent, due to the low risk nature of the study. This was approved on 22nd September 2014. In total, nine parents (1.1%) withdrew their child from the study. Copies of the information sheets for parents and students can be found in appendices one and two, respectively.

All students who had not been withdrawn from the study were subsequently informed about the research via a short presentation and information sheet. The students were encouraged to ask any questions they had before providing written assent, to confirm they were happy to participate. Two students chose not to participate, due to a reluctance to miss class. All students were informed of their right to withdraw at any time without consequence. Unless any student objected, all data that was collected up the point of withdrawal was retained for analysis.

Third was the sensitive nature of the research topic. One of the risks to the psychological well-being of the students was the potential for embarrassment about answering questions regarding their health. All questionnaire data was collected on school computers, therefore there was a risk that their peers could see their answers. To overcome this as much as possible, the students who completed the questionnaires were reassured that their answers were confidential and anonymous. Where possible, the classroom was arranged so that students sat separately, and were unable to see other computer screens. However, due to layout in some of the computer classrooms, this was not always possible. The REC also expressed concern that participating in research that involved thinking about a medical condition may elicit a negative physiological response from students, including an asthma attack. Although this was not experienced by any students, this was accounted for by ensuring that students were aware of their right to withdraw if they felt uncomfortable. All students and their parents were also advised of how to make a complaint, should this be necessary.

Fourth was the inconvenience placed on students, in particular missing lessons. To overcome this, the school was given full control over when the data should be collected, to ensure that disruption to the school day was kept to a minimum. Refreshments were also provided if the data collection occurred during a lunch break, catering for any dietary requirements that were notified by the school. In most cases (n = 21), the schools preferred to conducted the data collection sessions during lessons, with just three schools opting for an after-school session. Parents were made aware of the potential disruption to school lessons, prior to choosing whether to allow their child to participate.

No concerns were reported and no complaints were received by the students, the parents or the schools, during this study. Some students queried whether their names would be included in publications, however they were reassured that this would not be the case. Hard copies of confidential data were filed securely behind two locked doors, with access granted only to members of the research team on an ‘as needs’ basis. All online data was secured behind a firewall on a password protected computer. To ensure that complete anonymity of the students was maintained, all student names and identifiable data were replaced with non-identifiable reference

codes, comprising a sequence of numbers. School names were also replaced with numbers for the purposes of publication.

3.1.4 Data Collection Tools

The questionnaire included five compulsory sections and one optional section. There were 37 questions, including the questions in the optional section. A full copy of the questionnaire can be found in appendix three. Demographic information, including gender, age, ethnicity, postcode and additional health conditions, were also included. Where students did not know their postcode, the postcode of the school was used instead. Where it was not possible to complete the questionnaire online (e.g. where the internet went down in schools), a paper version was completed and uploaded. Due to technical difficulties with the school computers, 134 students at six schools completed the questionnaire on paper. Due to this, the compulsory sections could not be enforced, therefore some missing data was encountered. Students who had difficulty using computers, or with reading the questions, were supported by a member of school staff. All questions were multiple choice, with some additional free-text questions. The questionnaire took approximately 15 minutes to complete. Throughout the questionnaire, the terms "reliever" and "preventer" inhalers were used instead of SABA and Inhaled Corticosteroids (ICS).

Asthma Control Test (ACT)

The validated ACT is a five-item tool, and is a reliable method for assessing asthma control in children aged 12 and older [68, 141]. The license to use the ACT was gifted by GlaxoSmithKline (GSK) for research purposes. The tool was originally developed as a self-report measure to assess asthma control in patients, and it can be used in the clinical environment and at home. The ACT is designed to assess symptom frequency, use of short-acting β-agonists (SABA), night-time symptoms, activity limitations, and students' perception of their asthma control over the previous month. Each answer denotes a score of one to five. Scores on the ACT range from a minimum of five to a maximum of 25. Scores of nineteen or below indicate poor (suboptimal) asthma control; scores of twenty or above (optimal) indicate good asthma control. A recent European Respiratory Society taskforce recommends that an ACT score of 19 or less should trigger more intense clinical monitoring [144].

Adherence to Medication and Lifestyle Questionnaire

This section was developed by the research team. The aim of this section was to assess intentional and unintentional medication adherence, knowledge of medication, unscheduled access to healthcare services, school attendance and smoking behaviours. Although not validated, this part of the questionnaire was subject to rigorous testing, prior to being implemented in schools, as discussed above. Students were asked to their medications from a list, which included a picture and the clinical name. Students were encouraged to look up their medication on the internet if they could not recognise it from the list provided. There was also space provided for students to write down their medication if it was not included on the list. The students were also asked if they used a spacer.

The adherence questions assessed how comfortable students felt using their inhalers both inside and outside school. The responses were rated on a Likert scale, from one (not at all comfortable) to five (completely comfortable). Students were also asked to report if they ever missed their inhalers, either accidentally or deliberately. Free-text questions were also included to identify why inhalers were not taken as prescribed. The inhalers included the SABA inhaler (referred to as the "blue reliever inhaler" in the questionnaire); the ICS inhalers (referred to as the "preventer inhaler, often brown" in the questionnaire). Other medications were also included for students who may be on combination inhalers, including LABA.

Three questions were included assessing unscheduled visits to healthcare services over a four-week period. These questions included unplanned visits to the school nurse/first aider, GP and hospital, due to asthma. All responses were multiple choice and ranged from never to four or more times. Five school and lesson absences questions were also asked, using the same scale. The lifestyle section included three questions about whether the students themselves smoked, or whether they lived with anyone who smoked.

Me and My School Questionnaire (M&MS)

This section of the questionnaire was optional. The students who did not want to complete this section submitted their answers the rest of the questions and returned to class.

The M&MS questionnaire is a validated measure which was developed to assess emotional and behavioural well-being at school. The tool is validated for use in children aged eight years and older. Although used primarily in the school environment, the questionnaire can also be translated to the clinical setting [145]. The tool is a measure of a person's risk of developing any emotional or behavioural difficulties. The tool has good internal reliability, according to Cronbach's alpha, for both the emotional ($\alpha = .84$) and behavioural ($\alpha = .82$) scales.

The M&MS tool comprised two sections. In both sections, a statement about feelings was presented, and the students were asked to indicate their agreement with the statement. The emotion scale included ten items, and scores ranged from zero to 20. Similar to the ACT scoring system, a higher score indicates greater emotional difficulty. Scores between zero and nine indicate no emotional difficulty; scores of ten or eleven comprise borderline emotional difficulty; scores of twelve or above provide evidence of clinical emotional difficulty. The behavioural scale included six items, and scores ranged from zero to 12. Scores between zero and five suggest no behavioural difficulty; a score of six indicates borderline difficulty and a score of seven or above indicates clinical behavioural difficulty.

The inclusion of this measure within the assessment tool for this study was important, as evidence from America suggests that child mental health is a significant predictor of asthma morbidity. Children with clinically significant levels of behavioural problems experienced 18 additional days of wheeze per year, compared with children without these concerns [146].

3.2 Questionnaire - Pilot Study

3.2.1 Aims

There were four aims of the pilot study. The first aim was to confirm that the outcomes of interest could be adequately assessed using the online tool. The second aim was to assess the feasibility of the recruitment strategy and sample size, to ensure that it was suitable for the estimated timeframe. The third aim was to evaluate the accessibility of the online assessment tool for the target cohort. The final aim was to conduct preliminary testing on the current levels of asthma control and adherence to medication among teenagers with asthma in London secondary schools.

3.2.2 Methods

The pilot study was conducted between September and December 2014 in two East London secondary schools, one of which was an all-boys school. The students completed the online questionnaire in schools on computers, and the questionnaire took approximately 15 minutes to complete. Two members of the research team were present throughout the data collection session. Due to the small sample size, the results of the pilot study are descriptive only, and are reported separately to the main data.

3.2.3 Results

Demographics

The sample included 26 students across both schools (25 male and one female). The age of the students ranged from 12 to 18 years, with a median age of 13. Half of the students (n = 13) were of South Asian ethnicity. Seven students (26.9%) reported additional health concerns, including eczema (n = 2), Hayfever (n = 1), and food allergies (n = 2). One of the schools was a selective grammar school and the other was a state comprehensive. There was no missing data for any of the sections in the pilot sample.

Asthma Control

The scores on the ACT ranged from a minimum of nine to a maximum of 24, with a median score of 18 (IQR= 7). Suboptimal asthma control was seen in over half of the students (n = 15; 57.7%). Figure four depicts the full range of ACT scores from all of the students. Of the 15 students who scored 19 or less on the ACT, indicative of poor control, seven students (46.7%) felt that their asthma was either well or completely controlled. Three students (20%) recognised that their asthma was poorly controlled.

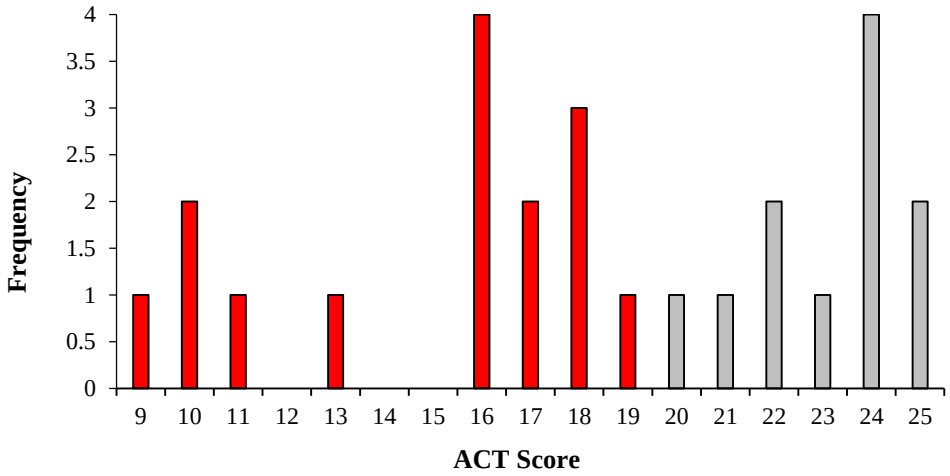


Figure 4. ACT scores from students in the pilot study

Medication Adherence

All the students reported having a SABA inhaler, referred to as a "blue reliever inhaler" in the questionnaire. Ten students (38.5%) were prescribed a SABA only; 16 students (61.5%) self-reported having an ICS inhaler, referred to as a "preventer inhaler" in the questionnaire. One student reported taking other medication, but was unable to identify it from the list and pictures provided. Eight students (30.8%) used a spacer with either some or all of their medications.

Eleven students (42.3%) felt either "somewhat", "hardly", or "not at all" comfortable using their reliever inhaler while at school; ten of these students (90.9%) had poor asthma control. Three students (11.5%), one of whom had poor asthma control, felt "somewhat" comfortable using their inhaler(s) outside school. Seven students (26.9%) said that they forgot to take their preventer inhaler either "sometimes", "most of the time", or "all of the time". Four of these students had poor asthma control (57.1%). Three students (11.5%) self-reported that they deliberately did not take their reliever inhaler, either "sometimes" or "most of the time"; and one of these students had poor asthma control. The reasons given by the students for not taking their inhaler(s) as prescribed included finding the inhaler a burden and feeling as though their symptoms were not severe enough to need an inhaler.

Unscheduled Care

In the four weeks prior to completing the questionnaire, seven students (26.9%) had at least one unplanned visit to see their GP due to their asthma; all these students had poor asthma control.

Six students (23.1%) had at least one unplanned visit to the hospital emergency department due to their asthma; five of these students had poor asthma control. Four of these students had also visited their GP for their asthma. Three students (11.5%) had also visited the school nurse/first aider at least once in the previous four weeks due to their asthma; all these students had poor asthma control. One student visited the GP, hospital and school nurse at least twice for their asthma in the four weeks prior to completing the questionnaire.

School Attendance

Three students (11.5%) had at least one complete school day absence, due to their asthma, in the four weeks prior to completing the questionnaire. Three further students reported at least a partial school day absence, due to their asthma, during the same time frame. All six of these students had poor asthma control. Three students missed all or part of a regular lesson at least once, and ten students (38.5%) missed all or part of a PE lesson in the four weeks prior to completing the questionnaire. Eleven of these students had poor asthma control. Seven students (26.9%) felt that their asthma had either "a little bit" or "some" negative impact on their school performance. All these students had poor asthma control.

Lifestyle and Smoking

None of the students in the pilot study said that they smoked. Four students (15.4%) reported that their parents/carers or anyone else they lived with currently smoked. Five students (22.7%) said that their parents/carers or anyone else that they lived with had previously smoked. Four students (15.4%) did not answer this question. Six of the students who reported that their parents/carers/household members either currently or used to smoke (66.7%) had poor asthma control.

M&MS Questionnaire

Twenty-one students (80.8%) were happy to answer additional questions about how they felt at school. Scores on the emotion scale ranged from zero to eight, with a median score of two (IQR = 1.5). The scores on the emotion domain also confirmed that none of the students had any borderline or clinical emotional difficulties. Scores on the behaviour domain ranged from zero to

ten, with a median score of two (IQR = 2). Eighteen students (85.7%) recorded a score of five or less, consistent with no behavioural difficulties. Two students (9.5%) had a score of six, indicating borderline behavioural difficulty. One student scored ten on the behaviour scale, indicative of clinical behavioural difficulty. Five students (23.8%) reported that they had experienced teasing or bullying at school because of their asthma. Three of these students had poor asthma control, according to their scores on the ACT.

3.2.4 Conclusion – Pilot Study

The findings from the pilot study showed that an online questionnaire was an effective strategy for assessing asthma control in a sample of secondary school students with asthma in London. Although preliminary, the findings presented here show concerning levels of poorly controlled asthma, according to scores on the ACT, and suggest that further investigation should be conducted, to see whether this continues in a larger cohort of teenagers.

The pilot study established that the online tool was appropriate for the target cohort, and could suitably be used to answer the research questions. Although the pilot study also demonstrated that the recruitment strategy was feasible, more time should be dedicated to recruiting the schools.

A key learning point from the pilot study was the absence of any knowledge data. The findings presented here are purely descriptive, due to the small sample size, however following analysis of the pilot data, it became apparent that the role of knowledge had not been investigated, and could be an important factor to include in a larger scale study, particularly when assessing the barriers to adherence among teenagers. Some of the free-text responses (e.g. “I think it is less likely that I will have to use it [the blue inhaler]”) indicate a lack of knowledge among some of the teenagers that participated, which could explain some of the high levels of poor adherence and poorly controlled asthma that were seen. To this end, for the full questionnaire, a series of three knowledge questions were included, regarding the role of their medication. The development of these questions will be discussed further in section 3.3.

Despite the small data set, these findings suggest that asthma, particularly poorly controlled asthma, can impact on quality of life for children and young people. A larger dataset is required to further understand some of the barriers to effective asthma management, as well as some of the

factors that could be targeted in a future self-management intervention, to improve asthma control for children and young people.

3.3 Questionnaire – Main Study

3.3.1 Aims

There were two primary aims of the main questionnaire study. The first was to assess current levels of asthma control among secondary school students in London, using the validated ACT. The second primary aim was to investigate the extent to which poorly controlled asthma impacts on quality of life for children and young people.

3.3.2 Methods

Recruitment for the main questionnaire started in March 2014 and ended in June 2015, when the final school participated. Schools were invited using several recruitment strategies. The project was initially advertised in a newsletter, produced by the Centre of the Cell (COTC), and was distributed to all schools within the COTC network. Following this, emails were sent to COTC partner schools in North and East London boroughs. After an initial low uptake, targeted methods, such as personalised emails and phone calls to heads of science, were implemented. The recruitment area was also widened to include all schools across London. Personalised emails were also sent to schools in London who were part of the QMUL 'widening participation scheme' [147]. This scheme invites all school students to participate in a variety of activities, including school-based workshops and university days at QMUL. The scheme is open to all students who are eligible for free school meals, or whose parents are from non-professional occupations, or did not attend higher education. Schools were also recruited at a STEM teacher conference in London. Table two shows the full recruitment strategy. All schools that showed an interest in the research were contacted via telephone to arrange a visit to discuss the project further.

Time Frame	Recruitment Strategy	London Boroughs	Schools Contacted	Participating Schools
March to June 2014	Mail and email shot	North East London	201	11
May 2014	Newsletter advertisement	North East London	-	1
May 2014	Email to partner schools of SHWRN	North East London	12	0
March 2015	Email shot	North East and South East London	102	0
May 2015	Targeted email to head of science	North East and East London	65	2
May 2015	Email shot	North West, South East and South West London	266	0
May to June 2015	Email to COTC visitors	All	26	1
June 2015	Email to QMUL widening scheme	All	9	5
June 2015	STEM teacher conference	All	-	1
June 2015	Email to Barts partner schools	East London	20	3
Total			**701**	**24**

Table 2. School Recruitment Strategy

As seen in table two, in excess of 700 schools were invited to participate, and 24 schools agreed, generating an approximate response rate of 3.4%. The participating secondary schools in the study reflected 2.5% of all secondary schools in London, according to government national statistics [148], and 5.8% of the secondary schools in participating boroughs [148].

Data were not available for the number of schools who received the COTC newsletter, or who were represented at the STEM conference. There was no upper limit regarding the number of schools that could participate, and the observational nature of the study meant that a power calculation for the minimum number of students was not required. However, the sampling was limited by a one-year time frame. The low uptake of schools is an important limitation of this study, which will be discussed in more detail in the discussion in chapter six. As seen in figure five, most of schools also came from North and East London, thereby limiting the generalisability of the results to other population groups (e.g. affluent populations in South-West London).

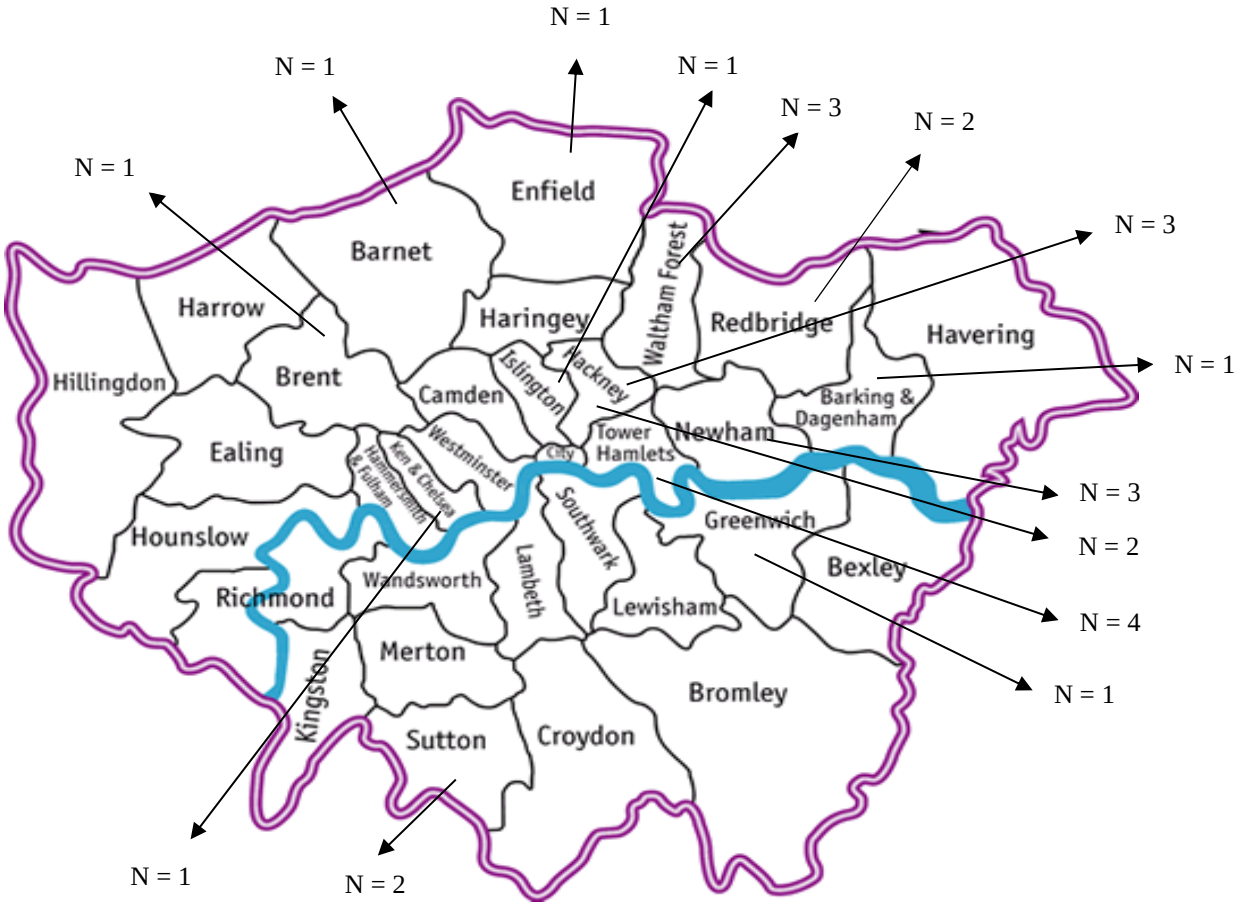


Figure 5. Distribution of participating schools

In addition to the 24 schools that participated, 20 further schools expressed an interest in the project, however they did not participate due to the school either being unable to accommodate the questionnaire (e.g. due to limited room availability), or the school contact subsided.

Once the interested schools had been identified, project information and withdrawal forms were sent to the designated teacher, for dissemination to the parents. The designated teacher at each school was also responsible for ensuring that the head teacher was happy with the school's involvement in the research; identifying eligible children within the school; organising a computer room for the data collection; and informing students of the session details. All students who were registered as asthmatic were invited to take part, and parents had two weeks to withdraw their child if they wished. The students were briefed on the research at the start of the data collection session, and they were given an information sheet to read and an assent form to complete, if they were happy to participate. The students were encouraged to ask questions, and not complete the assent form until they fully understood what was being asked of them. Once students indicated

that they were happy, they were directed to the online assessment tool. Figure six shows a photograph of the children completing the questionnaire; figure seven shows a screenshot of the website.

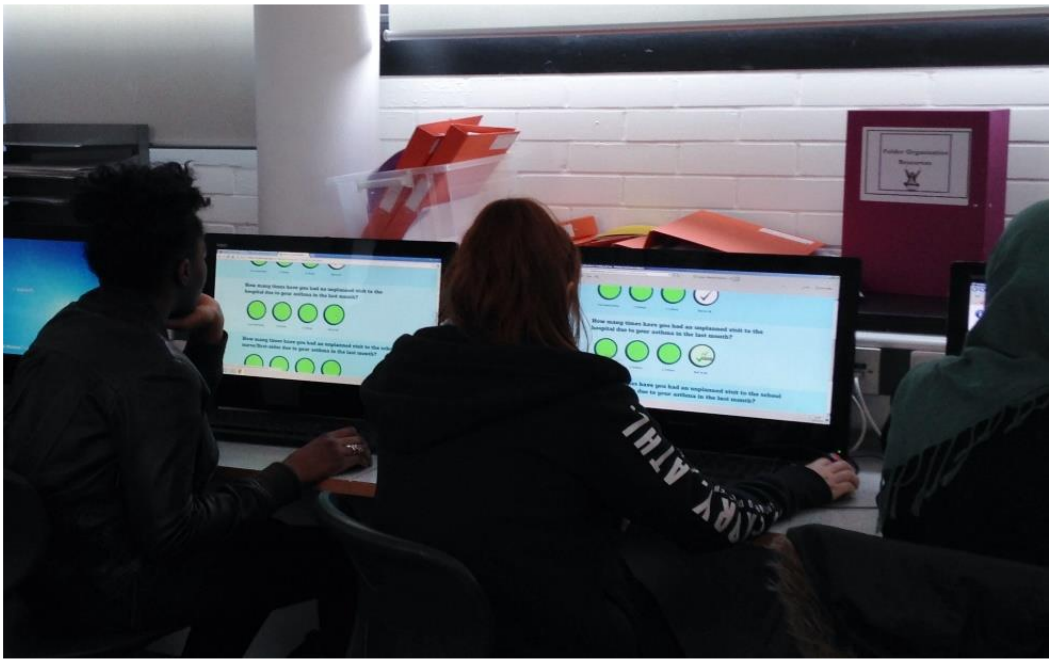


Figure 6. Photograph of students completing the questionnaire

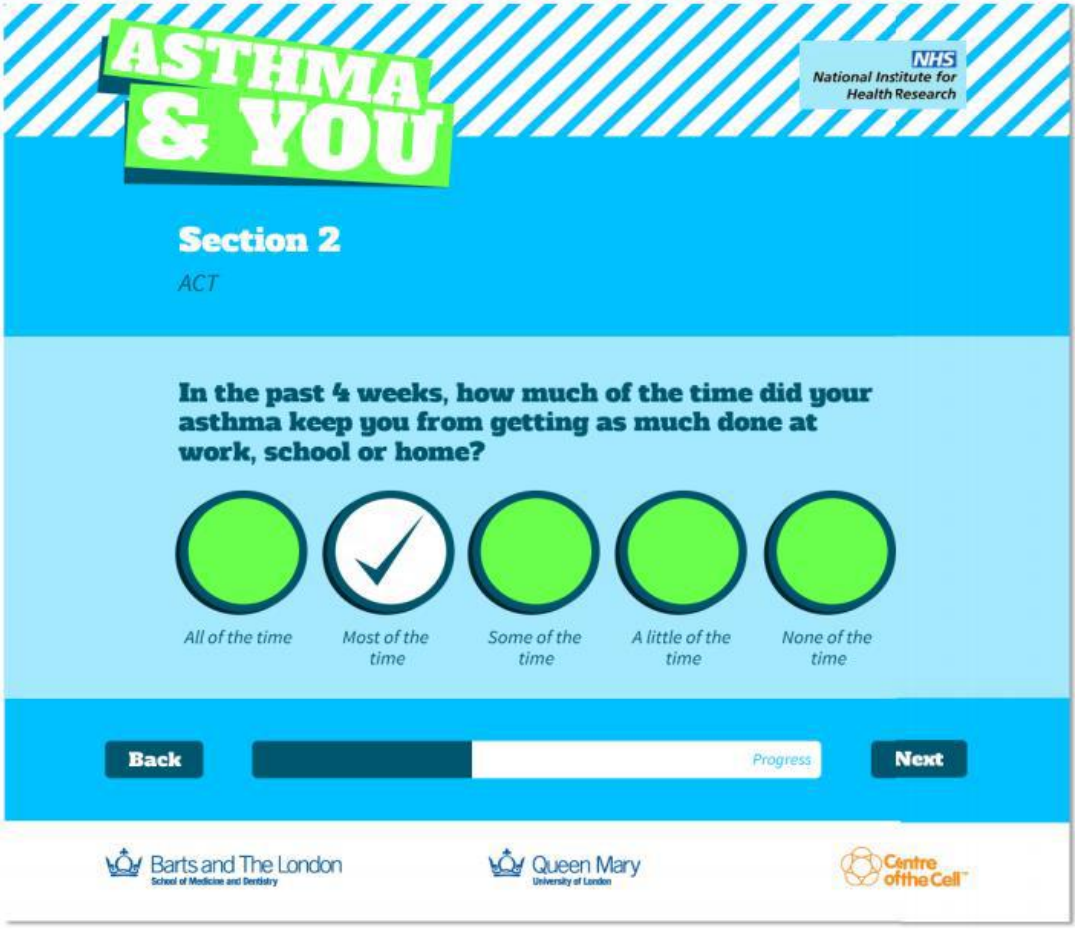


Figure 7. Online assessment tool

The questionnaire was administered online, and was accessed using a secure website (found here: https://www.myasthmaproject.co.uk). The students received a small goody bag as a thank you for their participation. To eliminate the risk of this being considered a bribe, the students were unaware of this incentive until after they had completed the questionnaire.

Attendance data was also requested from each school, to verify the self-report data on absence. Six schools sent this data, however the format of the data meant that it could not be used to verify student responses as all the information was anonymised. Moreover, the reason for the absence was unclear, therefore it did not confirm whether the absences were due to asthma specifically. The remaining schools were either unable to provide this information, or could not disclose this information to a third-party organisation.

Following the data collection, participating schools were offered learning opportunities with the COTC as compensation for their time. These opportunities included a free educational session at QMUL, or a careers workshop in school. It was surprising that uptake of these incentives was low; three schools accepted an educational session and three schools requested careers workshops, aimed primarily at their year eleven and sixth form students.

Statistical Analysis

All quantitative analyses were conducted using IBM SPSS statistical package (version 24). A p value of < 0.05 was considered statistically significant. Free text data was analysed qualitatively using thematic framework analysis. The data was non-parametric, therefore the findings are summarised as median (Interquartile Range (IQR)), unless otherwise indicated.

Continuous data were analysed using Spearman's rank order correlation co-efficient. Mann-Whitney U tests and chi-square analyses were performed on the categorical data to look for differences between the groups. Subgroup analyses were also conducted, based on gender, age and ethnicity. Previous epidemiological studies have shown differences in asthma control between gender and ethnicity groups. For example, being male is considered a risk factor for the onset of asthma up to age 16 [149]. Furthermore, in the UK, children from Caucasian and African ethnic backgrounds are at greater risk of experiencing asthma symptoms than children from South Asian ethnic backgrounds [150]. Conversely, children from South Asian and Black ethnic

backgrounds are at higher risk of hospital admissions following complications from their asthma, compared with children from Caucasian backgrounds [150].

3.3.3 Results

School Demographics

The participating schools included 20 state comprehensives, three grammar schools and one independent school. Most of the schools (n = 14) were co-educational, five schools were girls only, four schools were boys only and one school was mixed, however boys and girls were taught separately. Of the participating schools, 17 did not have a specific religion, six schools were Roman Catholic and one school was Anglican. The schools ranged in size from 704 pupils to 2576 pupils, with an average student body of 1323 pupils. According to the data provided by the schools, the total number of registered asthmatics in the participating schools ranged from 12 to 150, with an average of 61 asthmatics in each school. Two schools were unable to provide this information, and some schools did not wish to disclose this information. Notably, some schools did not have updated records of the registered asthmatic students in their schools, therefore the numbers of reported asthmatics are based on estimates and often result in an under-reporting of asthmatic children. According to online records, there were an estimated 31753 pupils registered across the 24 schools at the time of the data collection; the data provided by each school confirmed that there were an estimated 1279 asthmatic children registered across all the schools. This yielded an asthma prevalence of 4% across all the participating schools. Figure eight shows the prevalence of asthmatic students in the participating schools.

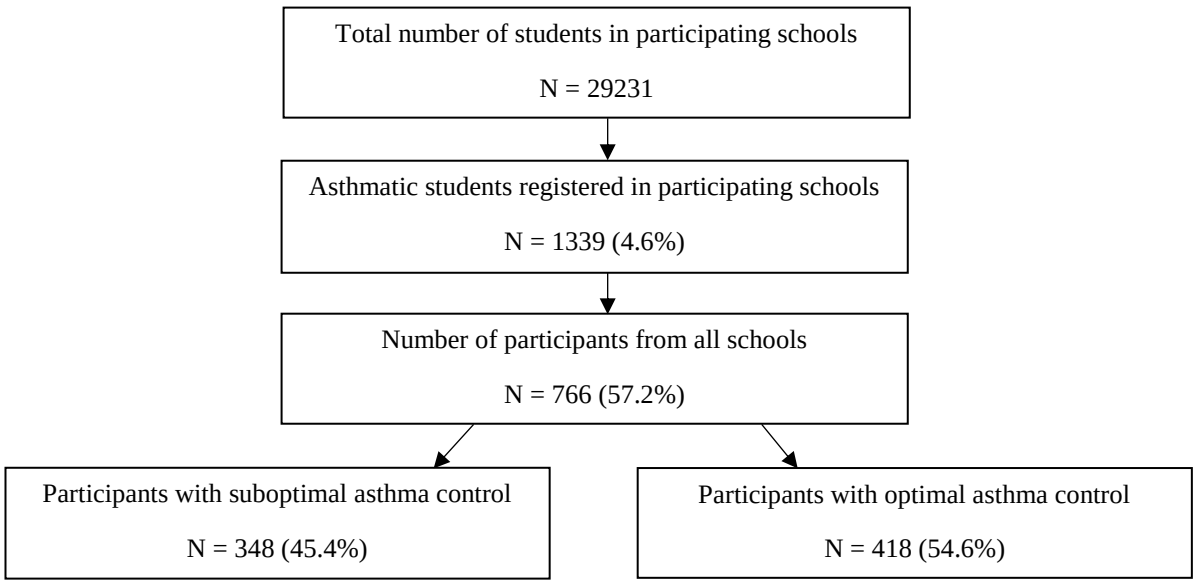


Figure 8. Prevalence of asthmatic students in participating schools

The number of participating students in each school ranged from a minimum of four to a maximum of 77, with an average of 32 asthmatic children participating per school. Table three gives the details of all of the participating schools. N/A denotes where the total number of students with asthma could not be obtained.

School ID	Type of School*	Total Students N	Method of Recording Asthmatics†	Reported Asthmatics N (%)	Asthmatic Participants N (%)	Suboptimal Control (%)	Median ACT Score (Units)
1	C	1236	TR	55 (4.4)	7 (12.7)	71.4	18
2	C	1211	I	N/A	57	47.4	20
3	C	1411	TR	40 (2.8)	20 (50)	40.0	20.5
4	C	1023	TR	68 (6.6)	64 (94.1)	53.1	19
5	C	2000	TR	20 (1)	15 (75)	60.0	19
6	C	2576	TR	24 (0.9)	8 (33.3)	37.5	21
7	C	967	TR	46 (4.8)	22 (47.8)	59.1	18
8	I	1345	I	N/A	17	17.6	21
9	G	898	TR	150 (16.7)	77 (51.3)	40.3	20
10	C	1145	TR	78 (6.8)	52 (66.7)	40.4	21.5
11	C	1518	TR	60 (4.0)	17 (28.3)	29.4	22
12	C	1104	TR	40 (3.6)	10 (25)	50.0	20
13	G	888	TR	59 (6.6)	39 (66.1)	38.5	21
14	C	1256	TR	12 (1.0)	10 (83.3)	50.0	18.5
15	C	1361	TR	40 (2.9)	30 (75)	40.0	21
16	C	1972	TR	61 (3.1)	49 (80.3)	49.0	20
17	C	1659	TR	102 (6.1)	43 (42.2)	44.2	20
18	G	1185	TR	99 (8.4)	61 (61.6)	39.3	21
19	C	1130	TR	50 (4.4)	26 (52)	61.5	18.5
20	C	1341	I	N/A	4	50.0	19.5
21	C	704	TR	34 (4.7)	34 (100)	50.0	19.5
22	C	1974	TR	90 (4.6)	59 (65.6)	66.1	17
23	C	951	TR	70 (7.4)	9 (12.9)	22.2	23
24	C	898	TR	81 (9.0)	36 (44.4)	30.6	21

Table 3. Details of participating schools

*C = Comprehensive; I = Independent; G = Grammar

†TR = Teacher Reported; I = Informal

Child Demographics

The main study was conducted from December 2014 to October 2015, and included 799 children aged 11 to 18 with asthma. Following the removal of incomplete ACT responses, 766 datasets were retained for analysis. In six schools, a temporary lack of internet connectivity prevented the questionnaire from being completed online, therefore identical paper versions were disseminated in these schools instead. The paper version of the questionnaire could not control instances of missing data in the same way as the online questionnaire, therefore 33 students (4.1%) failed to answer one or more of the ACT questions, and were subsequently removed from the dataset as ACT scores could not be calculated, thereby affecting the primary outcome. Seventy-three students with complete ACT datasets had missing data for other questions, representing 9.5% of the sample, however these students were not removed from the dataset.

A table detailing the total number of responses and missing data can be found in appendix four.

Within the final cohort, 315 students (41.1%) were female and 446 (58.3%) were male. Five students chose not to disclose their gender. The students' ages ranged from 11 to 18 years, with a median age of 13 years. The sample included children of predominantly Black (22.2%) and White (16.6%) ethnicity. Twenty-three students did not divulge their age or ethnicity, and five students chose not to disclose their gender. In addition to asthma, 506 students (66.1%) self-reported having no further health problems. The most commonly reported health concerns included Hayfever (n = 79); eczema (n = 77); and allergies (n = 63). Full details of the student's demographic information can be found in table four.

Demographics	N (%)
Age of Students	
11	92 (12.0)
12	149 (19.4)
13	153 (20.0)
14	143 (18.7)
15	113 (14.8)
16	32 (4.2)
17	39 (5.1)
18	22 (2.9)
Missing Data	23 (3.0)
Gender	
Male	446 (58.2)
Female	315 (41.1)
Missing Data	5 (0.7)
Ethnicity	
White	123 (16.1)
Black	165 (21.5)
Bangladeshi	95 (12.4)
South Asian	34 (4.4)
East Asian	22 (2.9)
Mixed	92 (12.0)
Other	212 (27.7)
Missing Data	23 (3.0)

Table 4. Demographic characteristics of participating students

Most of the students (n = 689; 89.9%) self-reported using medication for their asthma. Almost all the students could identify their medications from the photographs and the list provided in the questionnaire; 58 students (7.6%) were unable to identify their medication following an examination of the list provided and an internet search. Table five details the prescribed asthma therapy of the students.

Asthma Therapy*	Matched Medication	N (%)
Inhaler		
Blue	Salbutamol	648 (84.6)
Red	Ciclesonide	4 (0.5)
Purple	Fluticasone/Salmeterol	57 (7.4)
Red	Budesonide/Formoterol	30 (3.9)
Brown	Budesonide	19 (2.5)
Brown	Beclometasone	328 (42.8)
Orange	Fluticasone	6 (0.8)
Green	Salmeterol	28 (3.7)
Tablets		
Oral Steroid		14 (1.8)
Theophylline		0
Montelukast		25 (3.3)
No prescribed inhaled or oral medication		77 (10.1)
Prescribed medication not identified		58 (7.6)
Other±		39 (5.1)

*Colour picture and the name of the medication was included in the questionnaire
±Students certain that they had medication, but uncertain what it was
Table 5. Prescribed asthma therapy among participating students

Asthma Control

Scores on the ACT ranged from a minimum of six to a maximum of 25. The median score was 19.3 (IQR = 6). Suboptimal asthma control, indicated by a score of 19 or less on the ACT, was seen in 350 students (45.7%). Figure nine highlights the range of asthma control test scores among students.

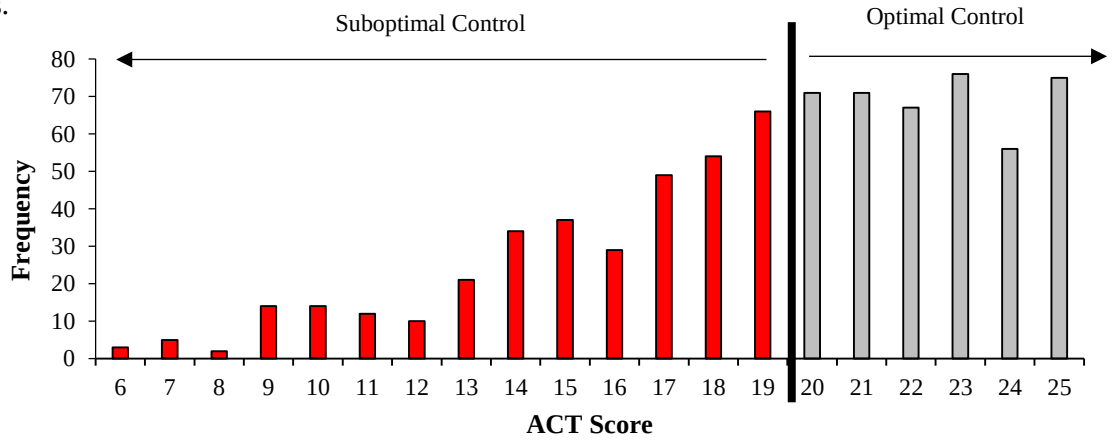


Figure 9. ACT scores of participating students

Of the 77 students (10.1%) who self-reported that they did not have any prescribed medication for their asthma, 36 (46.8%) scored 25 on the ACT, indicating an absence of symptoms; eight students (10.4%) scored 19 or less. Table six details the distribution of self-reported prescribed medication across the two asthma control groups.

	Total N (%)	Suboptimal Control N	Optimal Control N
SABA only	217 (28.3)	75	142
ICS only	295 (38.5)	160	135
LABA only	2 (0.3)	1	1
Combination ICS and LABA	84 (11.0)	61	23
Could not identify medication	58 (7.6)	33	25
No prescribed therapy	77 (10.1)	8	69

Table 6. Distribution of prescribed inhaler medications across the asthma control groups

Among the students who scored 19 or less on the ACT, 42.3% (n = 148) felt that their asthma was either well or completely controlled. Similarly, 15.1% (n = 53) acknowledged that their asthma was either poorly controlled, or not at all controlled. Of the students who scored 20 or above on the ACT, 1.7% (n = 7) felt that their asthma was either poorly controlled or not controlled at all. All students who scored 25 on the ACT (n = 75) identified that their asthma was completely controlled; however, 26.4% (n = 19) felt that their asthma had not gone away.

The students were asked how comfortable they felt using their SABA (blue) inhaler at school; 592 students responded. As seen in figure ten, 17.1% of students (n = 101) felt either not at all comfortable, or hardly comfortable, using their inhaler at school; 38.2% (n = 226) felt completely comfortable using their inhaler at school.

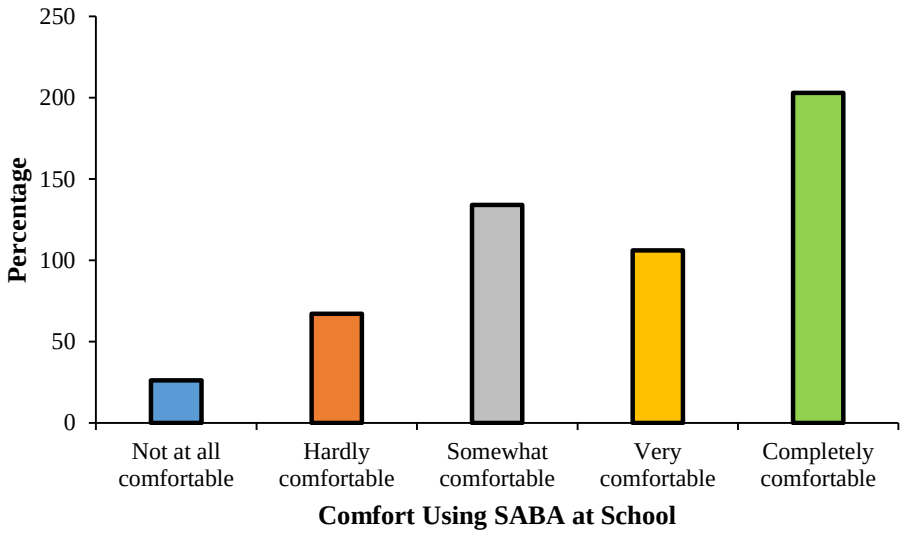


Figure 10. Distribution of how comfortable students felt using their SABA inhaler at school

Table seven compares this data across the two asthma control groups. The children with well controlled asthma felt more comfortable (very or completely) using their inhaler at school, compared to their peers with poorly controlled asthma (70.4% vs 47.9%).

	Total N (%)	Suboptimal Control N (%)	Optimal Control N (%)	P value*
	N = 536	**N = 303**	**N = 233**	
				<0.01
Not at all comfortable	26 (4.9)	19 (6.3)	7 (3.0)	
Hardly comfortable	67 (12.5)	50 (16.5)	17 (7.3)	
Somewhat comfortable	134 (25)	89 (29.4)	45 (19.3)	
Very comfortable	106 (19.8)	58 (19.1)	48 (20.6)	
Completely comfortable	203 (37.9)	87 (28.7)	116 (49.8)	

*by chi-square test

Table 7. Comfort using SABA inhaler at school

As seen in table eight and figure 11, 60.1% (n = 458) felt completely comfortable using their inhaler(s) outside school; 64.1% (n = 25) of those who did not feel comfortable using their inhaler(s) outside school had poor asthma control. Furthermore, 36.7% (n = 168) of those who felt completely comfortable using their inhaler(s) outside school had poor asthma control.

	Total N (%)	Suboptimal Control N (%)	Optimal Control N (%)	P value*
	N = 762	**N = 347**	**N = 415**	
				<0.01
Not at all comfortable	14 (1.8)	9 (2.6)	5 (1.2)	
Hardly comfortable	25 (3.3)	16 (4.6)	9 (2.2)	
Somewhat comfortable	98 (12.9)	55 (15.9)	43 (10.4)	
Very comfortable	167 (21.9)	99 (28.5)	68 (16.4)	
Completely comfortable	458 (60.1)	168 (48.4)	290 (69.9)	

*by chi-square test

Table 8. Comfort using inhaler(s) outside school

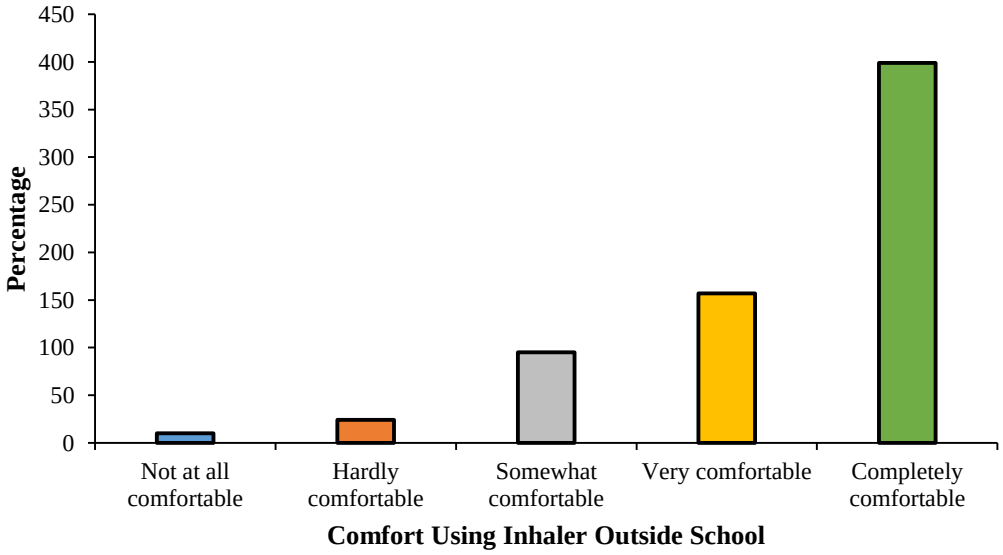


Figure 9. Distribution of how comfortable students felt using inhaler(s) outside school

Just under half of the students (49.5%; n = 379) self-reported using an inhaled corticosteroid ICS inhaler, either alone or with a LABA inhaler (referred to as a "preventer" inhaler in the questionnaire, in accordance with the BTS guidelines [151]). When asked what this inhaler was for, 37.4% of students (n = 142) were unable to identify the correct answer. Chi-square analysis revealed that asthma control was not associated with knowledge about the ICS inhaler ($p = .545$). A spacer was used by 40.8% of students (n = 311); 46.6% (n = 145) used a spacer with some of their inhalers; 53.4% of students (n = 166) used a spacer with all their inhalers. Adherence with the spacer was low: 38.7% (n = 120) self-reported that they used their spacer either less than half the time, or never; one student did not respond. When asked to identify the role of their spacer, 16.1% of students (n = 48) did not know. Chi-square analysis revealed that there was a significant difference between the two asthma control groups and knowledge of the spacer ($p = .033$); and Mann-Whitney U analyses confirmed that knowledge of the spacer was significantly higher among students with poor asthma control ($p < .05$).

Demographic characteristics, including gender and ethnicity, were not associated with asthma control, according to the subgroup analyses. A significant positive correlation was seen between ACT scores and age; however, this association was very weak ($r = .168$, $p < .01$). The proportion of asthmatic students with poor asthma control, according to the ACT, was higher in non-selective (otherwise known as comprehensive) schools, compared with selective (grammar and independent) schools (48.4% vs 37.6%; $p <.05$).

Medication Adherence

As mentioned above, just under half of the students self-reported using an ICS with or without a LABA inhaler. Table nine shows the adherence data for this; figure 12 shows the prevalence of non-adherence with this inhaler. More than half of the students (55.4%; n = 247) self-reported forgetting to take their inhaler either "sometimes", "most of the time", or "all of the time".

	Total N (%)	Suboptimal Control N (%)	Optimal Control N (%)	P value*
	N = 446	**N = 253**	**N = 193**	
				< 0.01
All the time	47 (10.5)	21 (8.3)	26 (13.5)	
Most of the time	82 (18.4)	54 (21.3)	28 (14.5)	
Sometimes	118 (26.5)	74 (29.2)	44 (22.8)	
A little of the time	119 (26.7)	71 (28.1)	48 (24.9)	
Never	80 (17.9)	33 (13.0)	47 (24.4)	

*by chi-square test

Table 9. Adherence with the ICS +/- LABA inhaler, by asthma control group

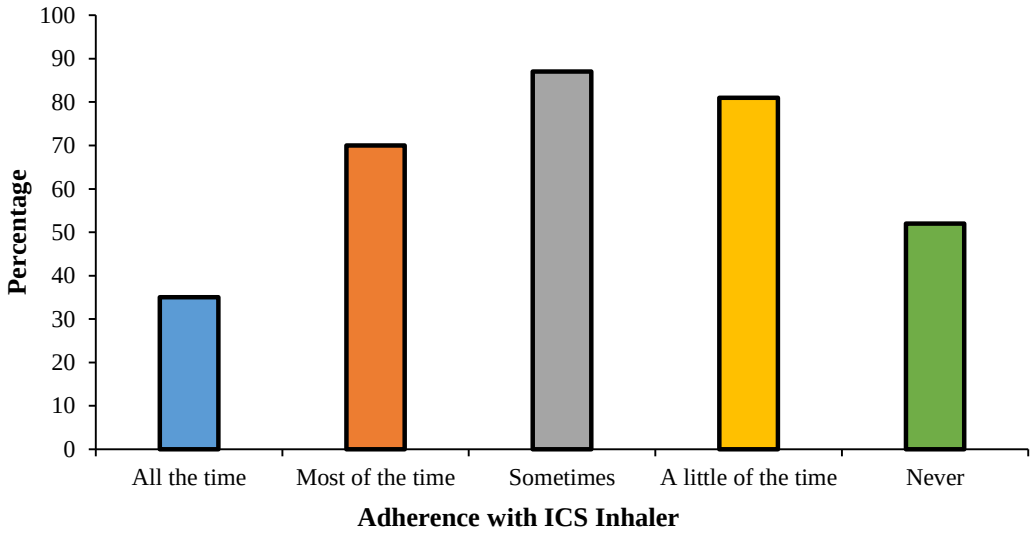


Figure 12. Non-adherence with the ICS +/- LABA inhaler

In addition, 23.0% of students (n = 101) also self-reported that they missed this inhaler deliberately either "sometimes", "most of the time" or "all of the time". According to the 181 free-text responses, the most frequently reported reason for nonadherence with this inhaler was forgetfulness, with some students expressing difficulty in remembering to take their inhaler in the morning when they were getting ready for school, or in the evening when they were doing homework or extracurricular activities. Other reasons included a belief that the ICS +/- LABA inhaler was necessary because the symptoms were not severe enough symptoms. The full range of responses are given in table ten.

Reason	Example	N
Forgetfulness	"I sometimes forget because it is not in my priority list of things to do"	70
Not needed	"I do not really need it all the time"	47
Inconvenience	"It takes a long period of time to get the right exact amount of medication"	23
Side-effects	"It is disgusting and too strong"	6
Ineffective	"I do not feel like it helps much, even when I use it, so I tend to forget it is there"	6
Use SABA instead	"Sometimes I forget because I'm more used to using the blue one"	5
Misplaced	"I can't find it"	5
Knowledge	"I did not know that I was meant to take a regular preventer inhaler"	5
Do not want to use it	"I want to cope without the help of my medication"	5
Laziness	"I can't be bothered to take it. I feel like there is no point, too much effort"	4
Uncomfortable	"I do not feel comfortable with it"	3
Do not know	"I do not know, to be honest"	2

Table 10. Free-text responses to reasons for non-adherence with the ICS +/- LABA inhaler

Chi-square analysis showed a significant interaction between asthma control and adherence to medication. A greater proportion of students with poor asthma control, according to the ACT, self-reported that they did not take their ICS +/- LABA inhaler, at least some of the time, compared to students with good asthma control, however the difference between the two groups was small (58.9% vs 50.8%, $p < .01$). A significant association was also seen between adherence with the ICS +/- LABA inhaler and knowledge of this inhaler ($p < .01$). A Mann-Whitney u analysis showed that adherence was slightly greater among those with increased knowledge of the inhaler, however this was not significant ($p = .978$).

A blue SABA "reliever" inhaler was reportedly used by 648 students. As seen in table eleven, 29% ($n = 176$) did not use their reliever inhaler when they needed it either "sometimes", "most of the time", or "all of the time". In total, 256 free-text comments were received detailing the reasons for non-adherence with this inhaler. The free-text responses are detailed in table twelve.

	Total N (%)	Suboptimal Control N (%)	Optimal Control N (%)	P value*
	N = 606	**N = 309**	**N = 297**	
				< 0.01
All the time	30 (5.0)	18 (5.8)	12 (4.0)	
Most of the time	43 (7.1)	29 (9.4)	14 (4.7)	
Sometimes	103 (17.0)	63 (20.4)	40 (13.5)	
A little of the time	164 (27.1)	77 (24.9)	87 (29.3)	
Never	266 (43.9)	122 (39.5)	144 (48.5)	

*by chi-square analysis

Table 11. Adherence with the SABA inhaler, by asthma control group

Adherence with the SABA inhaler was significantly lower among students with poor asthma control. A greater proportion of students with poor asthma control, according to the ACT, self-reported that they did not take their SABA inhaler when they needed it, at least some of the time, compared with students with good asthma control (35.6% vs 22.2% $p < .01$). No differences were found between adherence with the SABA inhaler and how comfortable students felt using this inhaler at school. Among the students who felt either "somewhat", "very", or "completely" comfortable using their inhaler at school (n = 443), 12.0% used their SABA inhaler when they needed it either all the time or most of the time. Among the students who felt either not at all comfortable, or hardly comfortable, using their inhaler at school (n = 93), 7.5% used their inhaler when they needed it either all the time or most of the time.

Reason	Example	N
Do not need it	"I think wheezing will get better on its own. I do not need an extra pump"	59
Learn to cope without it	"I want to learn to cope without my asthma pump"	58
No access to it	"Sometimes I do not have it on me"	45
Forgetfulness	"I forget about it"	32
Peer response	"Sometimes it is embarrassing in front of people/friends as you may be considered weak"	20
Misplaced	"I might have lost it"	9
Inconvenient	"When I am out of breath I am too tired to get it"	8
Side-effects	"Sometimes I do not use it because it makes me shake so it disrupts me"	8
Efficacy	"I do not feel it helps that much. I can usually get over wheeziness or an attack by myself"	5
Not sure	"I do not know"	4
Use preventer instead	"I usually use the brown inhaler"	4
Prescription expired	"I rarely suffer asthma attacks so my prescription was out of date"	3
Knowledge	"Sometimes I do not know when I need it"	1

Table 12. Free-text responses to reasons for non-adherence with the SABA inhaler

Tablets were prescribed to 39 students, according to the self-report data; 33 students answered the questions regarding adherence with their tablets. Over a third of these students (36.4%; n = 12) self-reported that they forgot to take their tablets at least some of the time. Free-text responses regarding reasons for non-adherence with tablets were collected from students and 53 responses were recorded. Like the adherence data for inhalers, the most commonly reported reason for non-adherence, according to the free-text data, was forgetfulness. The free-text responses are shown in table thirteen.

Reason	Example	N
Forgetfulness	"I forget to take my medication; it is hard to remember. These things are not on my mind"	20
Side-effects	"I do not like tablets. They taste horrible and I feel a bit sick"	9
Do not need them	"Sometimes I do not need them if I have not shown any symptoms of asthma"	8
Do not want them	"I do not like taking tablets because I worry they can hurt me"	7
Use different medication	"It is just easier to take an inhaler"	4
Do not know	"I just do"	2
Too many medicines	"There are too many tablets"	1
Embarrassment	"I do not want to take them in front of my friends"	1
Ineffective	"The prescription is too little"	1

Table 13. Free-text responses for reasons for non-adherence with tablets

Data was collected from 595 students on how they felt at school. A small number of students (5.7%; n = 34) reported that they had been bullied because of their asthma either "all the time", "a lot" or "a little bit". A further 6.8% of students (n = 39) preferred not to answer this question. No significant association was found between whether students were bullied at school and their adherence with their blue SABA ("reliever") inhaler. A significant association, however, was found between whether students were bullied at school due to their asthma and how comfortable students felt using their inhalers at school. The chi-square analyses also showed that a greater proportion of students who were bullied at school either "a little bit", "a lot" or "all the time" felt less comfortable taking their inhalers at school, compared with those who reported that they had not been bullied due to their asthma (38.5% vs 37.1%, $p < .01$), however the difference was very small. Among the students who reported experiencing being bulled due to their asthma, 88.2% (n = 30) had poor asthma control.

Unscheduled Care

Unscheduled care over a four-week period, including visits to a school nurse, GP and hospital emergency departments, were recorded by 743 students. At least one unplanned visit to see the school nurse was reported by 16% of students (n = 119). Four or more visits to the school nurse was reported by seven students (0.9%). At least one unplanned visit to the hospital emergency department, due to asthma, was reported by 15.7% of students (n = 117); four or more visits were reported by 1.2% of students (n = 9). Unplanned GP visits were much higher; 28.1% of students (n = 209) reported visiting their GP at least once. Notably, 2% of these students (n = 15) visited their GP four or more times due to their asthma during this period. The rates of unscheduled care across the asthma control groups are shown in table fourteen.

	Total N (%)	**Suboptimal Control N (%)**	**Optimal Control N (%)**	**P value***
Unplanned GP visits	**N = 743**	**N = 340**	**N = 403**	**< .001**
Never	534 (71.9)	185 (54.4)	349 (86.6)	
1-2 times	160 (21.5)	118 (34.7)	42 (10.4)	
2-3 times	34 (4.6)	26 (7.6)	8 (2.0)	
4 or more	15 (2.0)	11 (3.2)	4 (1.0)	
Unplanned hospital visits	**N = 743**	**N = 340**	**N = 403**	**< .001**
Never	626 (84.3)	248 (72.9)	378 (93.8)	
1-2 times	88 (11.8)	68 (20)	20 (5.0)	
2-3 times	20 (2.7)	15 (4.4)	5 (1.2)	
4 or more	9 (1.2)	9 (2.6)	0 (0)	
Unplanned school nurse visits	**N = 743**	**N = 340**	**N = 403**	**< .001**
Never	624 (84.0)	250 (73.5)	374 (92.8)	
1-2 times	87 (11.7)	60 (17.6)	27 (6.7)	
2-3 times	25 (3.4)	23 (6.8)	2 (0.5)	
4 or more	7 (0.9)	7 (2.1)	0 (0)	

Table 14. Rates of unscheduled care

Most of the students who had visited their GP four or more times over a four-week period due to their asthma 73.3% had poor asthma control (n = 11), based on their ACT scores. All of the students who visited the hospital emergency department and the school nurse at least four times had poor asthma control, according to the ACT. The distribution of unplanned medical attention is shown in figure 13.

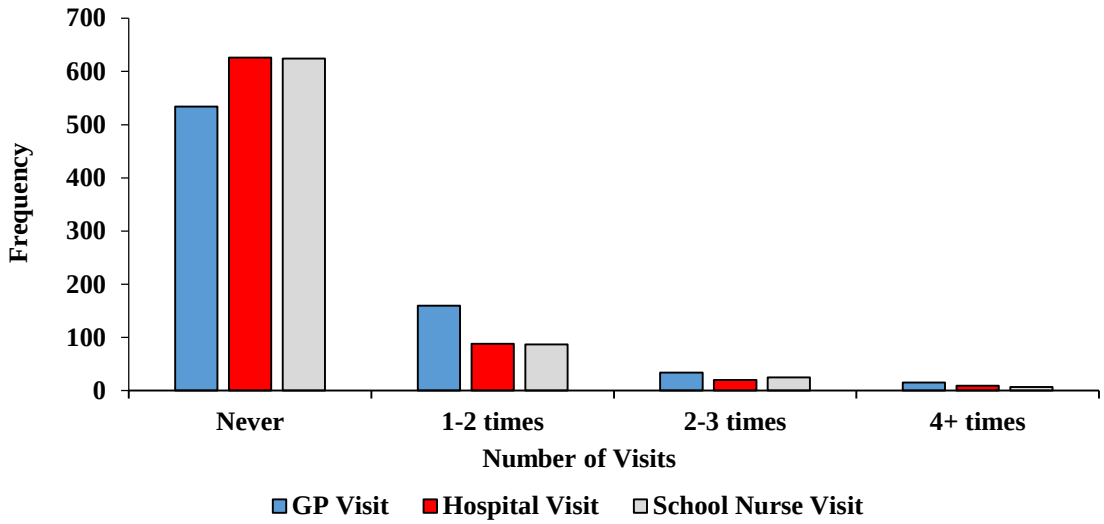


Figure 13. Unscheduled care over a four-week period

Higher rates of unscheduled GP visits were seen in students with poor asthma control, compared to students with good asthma control (45.6% vs 13.4%; $p < .01$). A greater proportion of students with poor asthma control also reported more visits to the hospital emergency department (27.1% vs 6.2%; $p < .01$) and the school nurse or first aider (25.7% vs 7.0%; $p < .01$), compared to students with good asthma control.

Chi-square analyses showed a significant association between unplanned GP visits and medication adherence. Among the students with at least one unplanned GP visit, 44% (n = 91) reportedly did not take their regular preventer inhaler at least some of the time ($p < .01$). No significant association was noted between medication adherence and unplanned hospital visits ($p = .073$); however of those who had at least one unplanned hospital visit (n = 117), 47% reportedly did not take their regular preventer inhaler as prescribed, at least some of the time.

School Attendance

School attendance data was collected by 738 students. At least one whole school day absence due to their asthma was reported by 20.9% of students (n = 154); 10.4% of these students (n = 16) had four or more whole school absences due to their asthma. Similarly, 17.6% (n = 130) had at least one absence from part of the school day. All or part of a regular lesson was missed at least once by 19.5% of students (n = 144); 6 students (4.2%) missed lessons four or more times. All or part of a Physical Education (PE) lesson was missed by 28.6% of students (n = 211). Table fifteen and

figure 14 show the proportion of school absences, due to asthma, across the two asthma control groups.

Total = 738*	Total N (%)	Suboptimal Control N (%)	Optimal Control N (%)	P value
Whole School Day				
	N = 738	**N = 336**	**N = 402**	
Never	584 (79.1)	226 (67.3)	358 (89.1)	**< 0.01**
1-2 times	120 (16.3)	85 (25.3)	35 (8.7)	
2-3 times	18 (2.4)	15 (4.5)	3 (0.7)	
4+ times	16 (2.2)	10 (3.0)	6 (1.5)	
Part School Day				
	N = 738	**N = 336**	**N = 402**	
Never	608 (82.4)	233 (69.3)	375 (93.3)	**< 0.01**
1-2 times	107 (14.5)	83 (24.7)	24 (6.0)	
2-3 times	15 (2.0)	13 (3.9)	2 (0.5)	
4+ times	8 (1.1)	7 (2.1)	1 (0.2)	
All/Part Lesson				
	N = 738	**N = 336**	**N = 402**	
Never	594 (80.5)	224 (66.7)	370 (92.0)	**< 0.01**
1-2 times	121 (16.4)	90 (26.8)	31 (7.7)	
2-3 times	17 (2.3)	17 (5.1)	0 (0)	
4+ times	6 (0.8)	5 (1.5)	1 (0.2)	
All/Part PE Lesson				
	N = 738	**N = 336**	**N = 402**	
Never	527 (71.4)	185 (55.1)	342 (85.1)	**< 0.01**
1-2 times	166 (22.5)	114 (33.9)	52 (12.9)	
2-3 times	29 (3.9)	26 (7.7)	3 (0.7)	
4+ times	16 (2.2)	11 (3.3)	5 (1.2)	

*Missing data from 28 students

Table 15. School absences across the asthma control groups

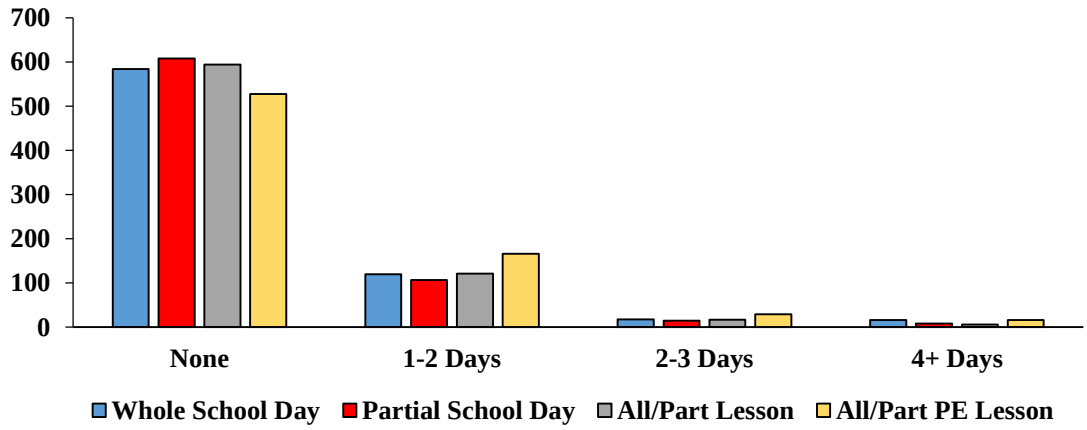


Figure 14. School attendance over a four-week period

Students with poor asthma control had significantly higher incidences of whole school day absences, compared to their peers with good asthma control (32.7% vs 10.9%; $p < .01$). This was also true for absences from PE lessons (44.9% vs 14.9%; $p < .01$). However, some students with

good asthma control were still reporting school and lesson absences, suggesting that their asthma may not be as well controlled as the ACT scores might suggest.

A quarter of the students (n = 4) who missed four or more school days due to their asthma had also visited their GP four or more times due to their asthma during the same four-week period; 31.3% of students (n = 5) who reported four or more school absences had not visited their GP at all. Similarly, 25% of students who had four or more school day absences (n = 4) had also visited the hospital emergency department at least once because of their asthma.

As shown in table sixteen, and figure 15, 96.6% of students (n = 740) reported on the impact of their asthma on their school performance. Either "some" or a "big" negative impact was felt by 16.5% of students (n = 12), 66.7% of whom (n = 12) had poor asthma control. Chi-square analyses found that a greater proportion of students with poor asthma control felt that their asthma negatively impacted on their performance school, compared to those students with good asthma control (27.1% vs 7.7%; $p < .01$). Similarly, 77.7% of students (n = 251) who felt that their asthma had no negative impact on their school performance had good asthma control.

	Total N (%)	**Suboptimal Control N (%)**	**Optimal Control N (%)**	**P value**
	N = 740*	**N = 336**	**N = 404**	
None	323 (43.6)	72 (21.4)	251 (62.1)	**< 0.01**
Hardly	176 (23.8)	88 (26.2)	88 (21.8)	
A Little Bit	119 (16.1)	85 (25.3)	34 (8.4)	
Some	98 (13.2)	75 (22.3)	23 (5.7)	
Big	24 (3.2)	16 (4.8)	8 (2.0)	

*Missing data from 26 students

Table 16. Impact of asthma on school performance

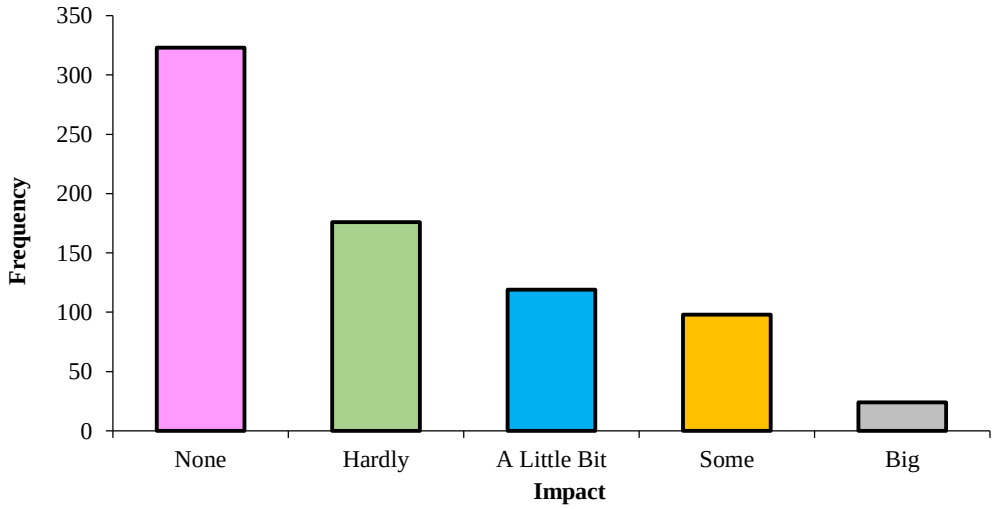


Figure 15. Impact of asthma on school performance

Sub-group analyses showed no significant association between ethnicity and whole school day absences (p = .232), lesson absences (p = .271) or PE lesson absences (p = .163). Similarly, no significant differences were seen between school attendance and gender.

Lifestyle and Smoking

A small number of students (5.1%; n = 39) reported that they currently smoked, 64.1% (n = 25) of whom had poor asthma control. Within this group, 20.5% (n = 8) reported that they smoked every day, and 46.2% (n = 18) said that they smoked less than once a week. Chi-square analysis showed no significant association between smoking and asthma control, however the proportion of students with poor asthma control who smoked was greater than the proportion of students with good asthma control who smoked (7.1% vs 3.4%; p = .177).

Among the 39 students who said that they smoked, 28.2% (n = 11) had visited their GP at least once for their asthma; 11 students had also visited the hospital emergency department. Four students who smoked said that they had been bullied because of their asthma, either a little bit, a lot, or all the time.

The students were also asked if their parents/carers/anyone they lived with currently smoked; 25.2% of students (n = 185) stated that they did. Of the 549 students who answered no to this question, 23.9% (n = 131) said that people in their household had previously smoked.

Emotional and Behavioural Wellbeing

The students were asked if they were happy to answer some questions about how they felt at school, using the validated 'Me and My School' (M&MS) questionnaire. Most students (79.9%; n = 612) were happy to continue to this section of the assessment tool. These students were aged 11 to 18 years (median = 13 years) and were 57.7% male.

Emotion Domain

Scores on the emotion scale ranged from a minimum of zero to a maximum of 20 (median = 3). Data was missing from 15 students. Most students had no clinical emotional difficulties, as indicated by the M&MS questionnaire (90.6%; n = 541). In total, 4.7% of students (n = 28) scored 10 or 11, indicative or borderline emotional difficulties; 4% of students (n = 24) scored 13 or

higher, indicative of clinical emotional difficulties, according to this measure. Figure 16 shows the range of emotion scores.

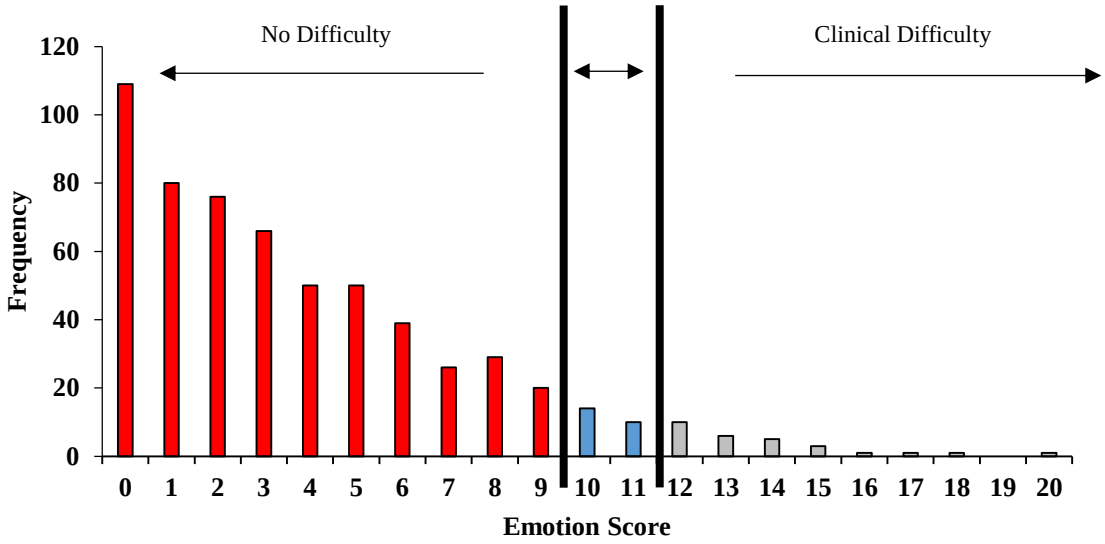


Figure 16. Emotion scores for participating students

There were 15 females (62.5%) and eight males (33.3%) in the borderline difficulty group. The clinical emotional difficulty group comprised mainly females (67.9%; n = 19). No significant correlation was seen between age and the scores on the emotion scale (r = .060; p = .148). A statistically significant difference was seen between gender and the emotion groups, with females showing higher levels of emotional difficulty (p < .01). No significant differences were seen between the emotion and ethnicity groupings p = .633).

A significant negative correlation was seen between scores on the ACT and scores on the emotion domain, however the association was weak (r = -.298; p < .01).

Among the students within the borderline group (n = 24), 20.8% (n = 5) felt that they had been bullied because of their asthma, at least a little bit. Among those within the clinical emotional difficulty group, 21.4% (n = 6) felt that they had been bullied because of their asthma, at least a little bit.

Behaviour Domain

Scores on the behaviour scale ranged from a minimum of zero to a maximum of 12 (median = 2). Data was missing from 19 students. Borderline behavioural difficulties, indicated by a score of six on the scale, were seen in 4.6% of students (n = 27). Clinical behavioural difficulties, indicated by a score of seven or higher, were seen in 7.4% of students (n = 44). Figure 17 shows the range of behaviour scores for the students.

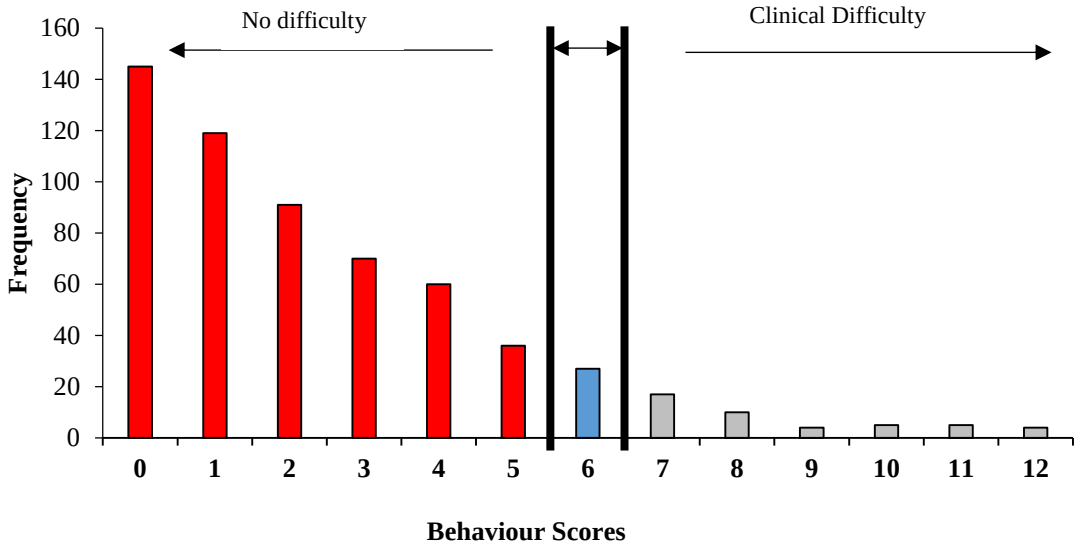


Figure 17. Behaviour scores for participating students

The students in the borderline clinical difficulty group included seven females (25.9%) and 20 males (74.1%). The clinical difficulty group included 17 females (38.6%) and 26 males (59.1%). Chi-square analyses found a significant difference between behavioural difficulty and gender ($p < .01$). Kruskal-Wallis analysis showed a non-significant association between behavioural difficulty and ethnicity ($p = .078$). No significant correlation was found between the age of students and scores on the behaviour scale ($r = .029$; $p = .480$). A significant correlation was seen between scores on the ACT and scores on the behavioural domain, however the correlation was very weak ($r = -.130$; $p < .01$).

Among the students with borderline behavioural difficulty (n = 26), one student (3.7%) self-reported that they were bullied all the time because of their asthma. Similarly, 6.8% of students (n = 3) with clinical behavioural difficulty, according to the M&MS tool, felt that they had been bullied because of their asthma either a lot or a little bit.

3.3.4 Discussion

The primary aim of this study was to assess asthma control in London secondary school students. The pilot study provided reassurance that an online questionnaire was an appropriate tool for collecting these data, and the results (discussed in section 3.3 of this chapter) highlight high levels of poorly controlled asthma, low levels of knowledge, and low levels of medication adherence among teenagers.

As discussed above, knowledge questions were included in the main questionnaire, following the outcomes of the pilot study. By including questions about knowledge, and allowing space for free-text responses for additional questions about medication adherence, this questionnaire begins to provide insight into some of the potential drivers of poor asthma control. As will be discussed further in section 3.4, additional focus groups will investigate some of these drivers more closely. However, what is evident from the questionnaire is that overall knowledge about the spacer is good, although knowledge about the ICS +/- LABA inhaler, and recognition of asthma symptoms, is concerning, particularly among those students with poor asthma control. This has also been seen in previous studies assessing knowledge of asthma among teenagers [152]. Although it can be hypothesised that low levels of knowledge may have contributed to the low levels of adherence that were seen here (although the existing evidence for this is low), data on the dose for the ICS +/- LABA inhaler, and the clinical justification for the medication, were not collected, therefore it is still unclear whether the poorly controlled asthma levels seen could also be due to inadequate treatment, poor adherence, or a combination of both. It also emerged from the findings that some children who scored 25 on the ACT were using a SABA inhaler, despite their responses suggesting that they had outgrown their symptoms. However, this only represented 4% of the students with asthma.

Over a third of the students with poorly controlled asthma felt uncomfortable using their SABA "reliever" inhaler at school. It could be that feeling uncomfortable taking medication in public contributes to rates of non-adherence with medication, and this will be examined further in the next steps of the research. However, the free-text responses collected here suggest that poor adherence is somewhat a conscious decision, with embarrassment and other social concerns

emerging as a leading barrier to good medication adherence. Other barriers included forgetfulness and inconvenience, which may be less of a conscious decision. These findings support qualitative evidence from Naimi *et al* [153], who collected adherence data from teenagers aged 15 to 18 years. Naimi *et al* also reported forgetfulness and medication ambivalence as frequent barriers to adherence among teenagers, as well as an incorrect perception of their own asthma control. As discussed earlier, there is also a possibility that some teenagers may normalise their asthma symptoms, and consequently have higher thresholds for seeking treatment [154]. This was also apparent in the findings presented here, as 42.3% of children believed that their asthma was either "well" or "completely" controlled. Although this may be common among young people, a delay in seeking treatment was noted in the National Review of Asthma Deaths [14] as a contributory factor to asthma-related deaths, therefore this behaviour should be addressed as early as possible to prevent any future avoidable mortalities.

3.4 Overall Conclusions

This study is the first in the UK to assess asthma control in secondary schools using the ACT. The results are, however, compatible with an international telephone survey, which was conducted in 2009 in children aged 4 to 15 years with poorly controlled asthma [74]. Two studies have been conducted in the UK in schools, however neither study assessed asthma control. In one study, conducted by McWhirter *et al* [76], quality of life, spirometry and inhaler technique was assessed in primary school children. In the second study, conducted by Patterson *et al* [155], asthma knowledge, school attendance, daily wellbeing, perceived self-efficacy, and quality of life were assessed in primary school children.

One of the strengths of this study (discussed further in chapter six), is that data were collected in the school environment. In doing this, the potential for students to be influenced by parents or clinicians was eliminated, including the potential of parents to influence the child to incorrectly report asthma control.

The findings of this questionnaire showed that delivering the questionnaire in schools, combined with using opt-out consent, was an acceptable and effective way of accessing children with

asthma. Therefore, the school could be an important space to consider for delivering interventions aimed at improving asthma control. However, the findings did also confirm that further investigations are needed regarding the potential barriers to medication adherence, which may be targeted in a future self-management intervention.

3.4.1 Justification for Methodology

These data were collected using an online questionnaire. This methodology had several advantages over a paper questionnaire.

First, the number of incomplete datasets was controlled and subsequently reduced, since I designed the website hosting the questionnaire to ensure that the children were unable to progress until all existing questions had been answered. Unfortunately, where technical difficulties in going online occurred, paper versions were used instead. It was the use of the paper questionnaire in six schools that contributed the vast majority of missing data. The online version also enabled students to complete the assessment tool faster, thereby reducing disruption to the school day, and potentially reducing boredom.

Second, the questionnaire was both timely and cost-effective to implement. Although the initial development of the software incurred higher expenses than the paper-based questionnaire, online questionnaires may elicit a higher response rate as they are more convenient for participants as they are completed instantly, with no expense incurred. Online questionnaires also save time in entering data manually into a database for analysis, and reduces the risk of error in doing so, as well as the risk of the hard copies being misplaced. Due to the immediate online responses, preliminary analyses can also be conducted on the data, to identify early trends that may emerge, allowing for initial planning of the next steps. The timely nature of the questionnaire also meant that multiple schools could be visited in one day, allowing the data collection to progress quickly.

Third, data collected in this study was more secure since they were immediately secured behind a password protected firewall. Anonymity could also be maintained through computer security measures.

Fourth, I speculate that the online approach enabled students to answer the questions honestly, since I was able to reassure students that their responses could not be traced back to them – something that I speculate may be less convincing in a paper questionnaire.

Plain Language Summary

The aims of the online questionnaire was to measure the current levels of asthma control and medication adherence among secondary school children with asthma. This questionnaire included the validated ACT, and questions on healthcare use, school attendance, knowledge of prescribed medications, lifestyle and smoking, and emotional and behavioural wellbeing, using the validated M&MS questionnaire. All of the questions included multiple choice answers, and some questions also included a free-text section.

The questionnaire was first tested on 25 children with asthma from two secondary schools in East London. This showed concerning levels of asthma control among the students, however the small sample size stopped any further analyses. The final sample included 766 children with asthma from 24 secondary schools in London. Recruitment to the main study took place over a 12-month period.

The findings from the questionnaire showed that 45.7% of the children had poor asthma control, according to the ACT. Knowledge of the spacer was generally high, although knowledge of the ICS $\pm$ LABA inhaler was much lower. Adherence with asthma medication was also low among most of the children. Some of the barriers to adherence included practical reasons, such as forgetfulness and inconvenience, however social barriers, including fears of being bullied, were also reported by the children. The findings also showed that children with poorly controlled asthma had higher levels of unplanned healthcare use, and more school absences.

Chapter 4. Assessing the Barriers to Adherence: Qualitative Work

4.1 Background

In chapter three, I found that asthma control, medication use, and knowledge of medication was low in a large proportion of children. I also found that healthcare use was greater, and school attendance was lower, among children with poorly controlled asthma, according to the ACT. However, a major limitation of these data is that children completed pre-assigned questionnaires with little or no options for explanations. To obtain further support of my hypothesis therefore requires more detailed exploration on the views and attitudes of affected children. I therefore chose to use a focus group format. In this chapter, I therefore discuss the development and the findings of the focus groups, and how the findings will be used to inform future work. The qualitative analysis that was conducted on this data used a 'light-touch' approach, and formal analyses were not conducted, although thematic framework analysis is widely recognised among qualitative researchers. This approach was used largely as the data collected during the focus groups was supplementary to the questionnaire data, and the primary aim was to further understand the barriers to medication adherence among teenagers, with a view to using this data to inform a future school-based intervention. As will be discussed in the methods section of this chapter, two independent researchers analysed the data, and I developed the themes according to the methods used in a qualitative paper that I previously worked on [156]. All themes were checked and discussed with a Health Psychologist for completeness.

4.1.1 Rationale for focusing on adherence

Non-adherence with asthma therapies contributes to increased rates of hospitalisations and deaths from asthma. The questionnaire data presented in chapter three showed that 29% of students did not take their blue SABA ("reliever") inhaler, and 56.4% did not take their ICS $\pm$ LABA inhaler as prescribed; of which, 23.2% self-reported that this was deliberate.

4.2 Focus Group Development

4.2.1 Sampling

The target population for the focus groups were secondary school students with asthma, who had participated in the earlier school-based questionnaire. The inclusion criteria was the same as that for the questionnaire data (discussed section 3.1.1). It was essential that the students had participated in the earlier online questionnaire, as the focus groups discussions were guided by the questionnaire content, therefore it was important that the students were familiar with the tool. All students who had completed the questionnaire were invited to participate in the focus groups. A power calculation was not required for this phase of the study, however Greenbaum [157] suggests that focus groups should ideally consist of between eight and ten participants. All schools from the first phase of the study were invited to participate, and four schools agreed. Reasons for non-participation included timetabling difficulties, including examinations, or a reluctance to take the students out of class for a second time. Some schools simply did not respond to the email invitation or subsequent phone calls. Two of the participating schools were located in East London (Hackney and Newham), one school was in South-West London (Sutton), and one school was in North-West London (Brent).

4.2.2 Ethics

Ethical approval for the focus groups was obtained via the Exeter REC (reference 14/SW/0120). A major amendment of the original application was submitted to the ethics committee, to include the focus groups in the data collection process. Ethical approval was granted on 1st September 2015. The ethical considerations were largely similar to those in the questionnaire phase, and are discussed in chapter three (section 3.1.3). These included child protection, the sensitive nature of the research topic, parental consent and disruption to lessons. Additional concerns raised by the REC, directly relating to the focus groups, included asking students to discuss their own health, and the potential psychological or physiological impact of participating in a discussion about asthma (e.g. concerns that the stress of discussing a sensitive topic may trigger an asthma attack). However, the focus groups were still considered to carry a low risk of harm to the students.

The information and consent procedure operated in the same way as the questionnaire phase (parental opt-out consent) and all students provided written assent. One parent withdrew their child from the focus groups. A copy of the information sheets can be found in appendices five and six. To ensure that the students were comfortable with the discussion topic, they were advised at the beginning of the session what would be discussed. All the focus groups were recorded using voice recorders only, with no video footage, to ensure that no data was missed during transcription and analysis. All parents and students were made aware of this before agreeing to participate. Due to the recordings, the students were also advised not to use their own, or anyone else's name, during the discussion, to maintain anonymity. If a name, or other identifiable data was recorded, this was replaced with a letter during transcription. All students and teachers were also advised that the discussions should not be repeated once students left the room. To ensure that students' did not feel pressured to discuss their own personal health, the discussion topics were kept very general, and students were not asked about their own asthma, and were not required to discuss their own personal experiences.

4.3 Aims

The primary aim of the focus groups conducted in this phase of my PhD was to further understand the barriers to adherence with asthma medications among teenagers in London. The secondary aim was to establish any strategies to improve adherence, which could be addressed in a future school-based intervention.

4.4 Methods

4.4.1 Recruitment and Data Collection

All schools who had previously participated in the online questionnaire were contacted, initially via email, and invited to participate in the focus groups. All emails were followed-up with a phone call to the designated teacher. Similar to the methods discussed in the questionnaire phase in chapter three, the teachers at participating schools were responsible for identifying the eligible

students and disseminating the information sheets to the parents. In all schools, the focus groups were conducted during lesson time, and each focus group lasted one hour.

The focus groups followed a semi-structured approach, facilitated by open-ended questions. The framework for the focus groups was informed by the outcomes of the questionnaire. These included a discrepancy between perceived and actual asthma control, non-adherence with medication, and low levels of knowledge about asthma. Therefore, and in accordance with the primary aim, the focus group discussions were primarily focused around barriers to adherence with asthma medication, with asthma control and knowledge of asthma used by the facilitators as prompts during the conversation. A full description of the focus group can be found in appendix seven.

The focus groups opened with an 'ice-breaker' game, in which the students were asked to finish a sentence starting "asthma is". The students were then read an experience of a fictional character with poor asthma control, according to the indicators within the ACT. The students were asked to identify the level of asthma control, and justify their response. To identify some of barriers to medication adherence, the students were asked what percentage of children they believed did not take their asthma medicines as prescribed, which was then compared with the data from the questionnaire. This triggered a discussion over the potential reasons for non-adherence. The role of knowledge in medication adherence was also discussed, as the evidence for this is mixed. Finally, ideas for a future school-based self-management intervention were discussed, including what topics should be covered during an intervention.

The sampling for the focus groups was limited by a nine-month time frame, from October 2015 to July 2016, to coincide with the end of the questionnaire data collection and the end of the academic year. A thematic framework approach was used for analysis, and all the data was analysed qualitatively using NVivo statistical package (version 11). Ethical approval was obtained for the focus group recordings to be transcribed externally by an independent transcription agency. A copy of the confidentiality agreement for this can be found in appendix eight.

4.4.2 Data Coding and Analysis

Qualitative analysis of the focus group data was undertaken for six months, from July 2016 to January 2017. Using thematic framework analysis, all the comments were coded and analysed by two independent researchers, to ensure that the coding framework was both comprehensive and not subject to bias by personal opinion. Thematic framework analysis was used as it provides a flexible, yet detailed overview of the data, and is considered a more accessible mode of analysis for researchers who are less experienced in qualitative research [158]. Thematic analysis is also typically used on a more structured dataset [159], such as this one, where the outcomes of interest were established in advance of the data being collected. As previously mentioned, the analysis methods that were used largely followed those used in a previous study [156], and also followed the recommendations made in an article by Smith and Firth, 2011 [160].

During coding and analysis, one focus group transcription was analysed separately by two researchers, one of whom was impartial and not involved in any other aspect of this PhD study, and was unaware of the aims of the focus groups. This ensured that all views and insight were representative of the data, and all discussions were not led by the desired primary outcome. Following analysis of the first transcript, the two researchers discussed their findings, and drafted a framework, based on the results. The first transcript was then analysed again, using the framework, and the framework was updated accordingly. This process was repeated until data saturation had been reached, and no further themes emerged. The same process was applied to all of the transcripts, and the framework was continually updated by one researcher, until data saturation had been reached on all six transcripts. Once this had been completed, the final framework was re-applied to each individual transcription for a final time to ensure that no comments or potential themes had been missed. A copy of the framework can be found in appendix nine.

4.5 Results

Demographic Characteristics

The focus groups included 58 students, which represented 7.6% of all those who completed the questionnaire and were included in the quantitative analysis. The focus groups were conducted in four secondary schools in London, all of which were state comprehensives. Two of the four schools were co-educational and the other two were girls only. The focus group sample included students aged 11 to 16 years (mean age 12.7 years). The sample was largely female (65.5%; n = 38). The proportion of female students was higher due to the inclusion of two all-girls schools, and is not an accurate reflection of the students in the first phase of the study, where the proportion of male students was higher than female students. A total of six focus groups were conducted; two schools each hosted two focus groups, and two schools held one focus group each. The size of the focus groups varied from eight to eighteen (mean = 15). The largest focus group exceeded the recommended maximum number of participants, however the REC advised that all students who expressed an interest should be included.

Descriptive Statistics

A total of 397 comments were coded and analysed, and five themes emerged. Within each theme, a number of sub-themes were also developed. To maintain the anonymity of the study, the free-text data could only be counted by the number of comments, rather than by the number of comments by different students. The five themes to emerge from the analysis included:

i. Asthma
ii. Medication adherence
iii. Communication
iv. Knowledge
v. Social impact

Table seventeen shows the total number of comments that were coded across all of the focus groups.

School	Theme 1: Asthma	Theme 2: Medication Adherence	Theme 3: Communication	Theme 4: Knowledge	Theme 5: Social Impact	Total
1	38	16	10	12	11	**87**
2	22	33	19	4	20	**98**
3	34	10	6	13	1	**64**
4	19	10	4	5	1	**39**
5	14	12	4	9	2	**41**
6	27	18	4	11	8	**68**
Total	**154**	**99**	**47**	**54**	**43**	**397**

Table 17. Total number of comments coded per theme

4.5.1 Theme One: Asthma

This theme referred to all generic comments about asthma. This included describing what asthma is and the impact of living with a diagnosis of asthma. This theme also included comments which described different levels of asthma control. There was widespread agreement among the students that asthma can have a negative impact on daily living and daily functioning, particularly if it is not well controlled, and this came through consistently. Asthma was described in several comments, many of which were non-specific. For example:

"Asthma is a disease that makes you breathe deeply"

"Asthma affects your lungs"

"Asthma is when you have different coloured pumps"

Other comments were negatively coded:

"Asthma is struggling for us and not everyone knows"

"Asthma is tough"

The remaining comments were more specific and were therefore coded into five sub-themes. Table eighteen highlights the sub-themes, accompanied by an example. Figure 18 displays the sub-themes as a graphic.

Sub-Theme	Example Quote
Asthma control	"It affects what you normally do, but not so far that you go to hospital"
Consequences	"Asthma is difficult sometimes because you can't concentrate on other stuff"
Embarrassment	"Asthma can sometimes make me feel embarrassed when I'm talking, like at school"
Medication	"Asthma means you need to take an inhaler to stop you from having an asthma attack"
Symptoms	"Asthma stops me from breathing"
Management	"Asthma is something that needs to be dealt with"

Table 18. Asthma sub-themes

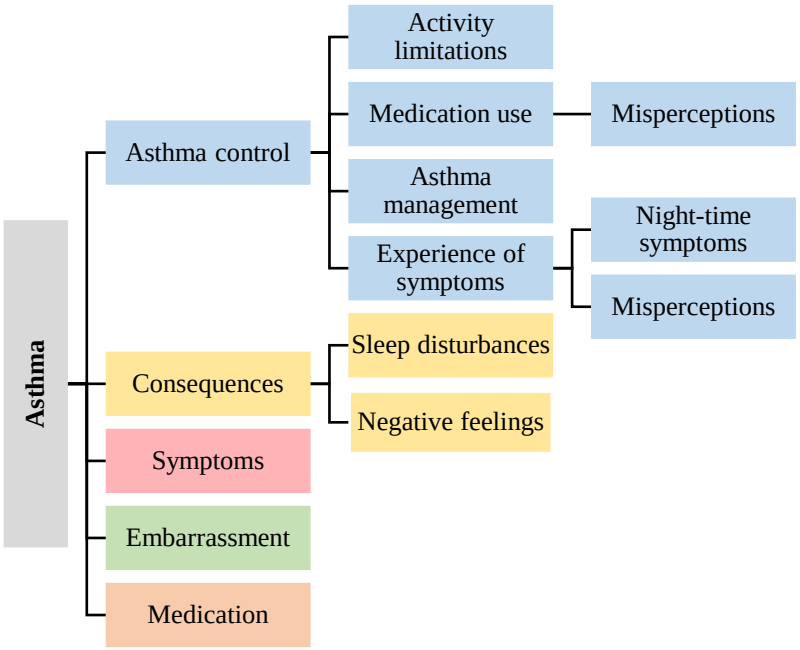


Figure 18. Asthma sub-themes

Asthma Control

Asthma control was the largest sub-theme. The comments here referred specifically to understanding of asthma control, and how asthma control can be characterised according to daily experiences. During the discussion, four key factors emerged that the student's associated with asthma control. These included activity limitation, medication use, asthma management, and asthma symptoms (figure 16).

Some students suggested that poorly controlled asthma would limit one's ability to do even minor activities. For example:

> *"When you have controlled asthma then you can do stuff like going upstairs and stuff. If you don't then it is kind of hard and makes you get short of breath"*

In accordance with the recommendations in the GINA guidelines for asthma control, some students discussed the impact of poorly controlled asthma on school and extra-curricular activities, and recognised how well controlled asthma can improve physical activity:

> *"Somewhat controlled wouldn't wake her up at night, but it is hard for her to do stuff at school"*

"You're not worried that when you are going to do an activity that you are going to be like, oh wait, I might feel breathless because if it is controlled then you really do not need to worry"

A second characteristic of asthma control was the use of medication. Many of the students could correctly identify that well controlled asthma should not require the use of the SABA inhaler:

"Good asthma control is when you can breathe properly, you don't need to use the blue pump regularly"

However, some of the students believed that good asthma control was characterised by using the inhaler to relieve the symptoms of asthma, rather than acknowledging that well controlled asthma should have minimal symptoms:

"I think well controlled is when it doesn't have to be that you're fine with it, it is just that you are using your asthma pump to help you do it, because then you are still controlling it. If your asthma is that bad then it is going to get worse, so at least they are doing their best to try and get rid of it"

Some students were also unable to correctly distinguish between the roles of the different inhalers. Instead, some students suggested that any inhaler could be used, instead of recognising the need for the inhalers to work together. However, it is unclear whether this comment came from a student who had been prescribed the SABA inhaler only or not:

"Poorly controlled because an inhaler is not helping, so maybe she should switch and use the blue one or something"

A handful of comments also suggested a misperception about asthma control, and demonstrated evidence of a higher threshold for symptom severity:

"I think it is well controlled because she has found out that her asthma is stopping her with short breaths, so she is using the blue inhaler"

"It is well controlled because she has only felt out of breath once or twice a week and it doesn't wake her up at night at all, and she has also been using her reliever inhaler"

Conversely, a small number of comments did show an awareness among some of the students of the differences between the SABA and ICS +/- LABA inhalers. These students did also demonstrate knowledge of how use of the SABA inhaler might alter, depending on level of control:

> *"Good control would mean that you do not have many of the symptoms and you only need to use your brown inhaler"*

> *"If your asthma is well controlled, you won't need your blue inhaler"*

Despite some of the comments above suggesting that some students were unaware of the relationship between asthma control and symptoms, there were some comments which showed how using medication can prevent asthma symptoms from getting worse. However, from this comment, it is unclear which inhaler the student is discussing:

> *"You don't have to wait until you have something to trigger it to use it, you take it not religiously, but so it just stops the asthma from happening"*

Some of the comments divulged that students associated good asthma control with an awareness of how to manage the symptoms of asthma. Some students considered knowledge an important component of maintaining good control of asthma symptoms:

> *"Good asthma control means when you know what to do when you think you have the symptoms of an asthma attack"*

The final characteristic of asthma control was the experience of asthma symptoms. This sub-theme referred primarily to the severity of the asthma symptoms, and the frequency of night-time awakenings as an indicator of control. This is in accordance with the indicators given in the ACT, and demonstrates an awareness of the seriousness of night-time awakenings:

> *"Somewhat controlled is finding it hard to breathe, but not getting all woken up. That would be poorly controlled if you get woken up. Well controlled is when it doesn't really happen"*

"Poorly controlled would be not controlled at all. It would be every single morning until night and not stopping"

Consequences of Asthma

The comments included within this sub-theme described some of the complications that can occur as a result of asthma, and the impact that asthma can have on daily well-being:

"Asthma is when you might need to go to hospital"

Within this sub-theme, sleep disturbances emerged, which was previously discussed in relation to asthma control as well. Unlike the discussions about asthma control, the comments regarding sleep disturbances were in the context of living with asthma, rather than as a result of poorly controlled asthma specifically. It is unclear whether the comments came from students with good or poor control, however the comments do give insight into the realities of living with asthma:

"Asthma is hard because it doesn't let me sleep at night"

"Asthma cannot let me have my rest and peace"

Some of the comments also highlighted the negative feelings that can be associated with asthma. For example:

"Asthma is a bad feeling"

"Asthma is stressful"

Asthma Symptoms

The third sub-theme within the asthma code was the experience of asthma symptoms. Some of the comments referred to the challenges of breathing:

"Asthma stops me from breathing"

"Asthma affects me when I am sick or something"

Medication use

All of the comments that were included here were non-specific and simply described asthma in terms of the medication that can be prescribed. For example:

"Asthma means that you need to take an inhaler to stop you from having an attack"

Embarrassment

Embarrassment about having a diagnosis of asthma emerged during the discussion about asthma as a condition, and some students identified feelings of embarrassment in social situations:

"Asthma can sometimes make me feel embarrassed when I am talking, say like in school"

However, some comments did also discuss asthma more positively:

"I don't think anyone should feel embarrassed"

4.5.2 Theme Two: Medication Adherence

The second theme that came out of the coding was medication adherence. Under this theme, the most prominent barriers to adherence in adolescents were identified. In contrast to the findings from the questionnaire, most of the comments implied a conscious decision for non-adherence. Table nineteen shows the barriers to adherence that were discussed.

Barrier	Sample Quotation
Unpleasant side-effects	"The taste makes me feel so sick"
Inhaler apathy	"They just can't be bothered to take it"
Forgetfulness	"They have to do work and homework and stuff so they forget"
Embarrassment	"Sometimes you might feel embarrassed to take it in front of your friends"
Reluctance to use in public	"They might feel embarrassed because loads of people are around"
Inconvenience	"They might be rushing to get somewhere"
Use a different inhaler	"I don't use my brown one"
Excuse to miss class	"Some people use it to get out of lessons"
Fear of reliance	"You don't want to rely on an inhaler to have a long-distance run"
No symptoms	"They don't need it"
Inhaler efficacy	"They can control it without an inhaler"

Table 19. Barriers to adherence among teenagers

Unpleasant side-effects

Unpleasant side-effects were the most commonly reported barriers to adherence. Most of the students commented on the unpleasant side-effects and how these contributed to adherence behaviours:

> *"Sometimes there are days when I take my inhaler and then I feel sick, so I just don't take it because the taste makes me feel so sick"*
>
> *"I hate that feeling when I get shaky after, that's why I don't take my pump a lot because I don't like the feeling of being shaky"*

Some other comments referred to the unpleasant side-effects, however the comments did not indicate whether this contributed to non-adherence. Indeed, there was also some evidence that the side-effects of medication were not a barrier to adherence:

> *"I have severe asthma and sometimes when it is really bad I have to take steroids, the tablets, and they taste really horrible, so I just hold my nose, and I know it is good for me so I just carry on taking it"*

Apathy

The second barrier to adherence was apathy towards either the medication or asthma. Several of the comments suggested that non-adherence may be due to some people not wanting to acknowledge their asthma:

> *"Maybe they just don't want to take it because they don't want to have asthma, so they just ignore it"*

A feeling of lethargy also came through in some of the comments. For example:

> *"I think most young people wouldn't take their inhalers because they are not really bothered to do it. They probably think it will be wasting their time, and there is no point of doing it anyway"*

Apathy towards the medication appeared to be associated with a lack of awareness about medication. The comments highlighted a common belief that teenagers and young people can cope without their inhalers, therefore they decide not to use them.

"They might think they don't need to use it, or that it's a joke or something"

Forgetfulness

Some students noted that people may forget their inhaler because of other demands on time, particularly for teenagers who have school or homework:

"Many people forget because of the stuff they do around, like they have work or homework and stuff and then they forget to take it"

"I don't know anyone who has a brown inhaler who remembers to take it all year round"

However, some of the comments suggested that forgetfulness is dependent on how seriously people take their asthma. For example:

People might forget their inhaler because some people in the world don't really care about their asthma and their health, whereas some people do"

Embarrassment

The social impact of asthma was a clear source of embarrassment. One student also mentioned how this is worsened by the way asthma is portrayed in the media:

"Say if they are hanging out with new friends, they might think that they are trying to impress them, they might think if they start taking their asthma pump, their friends might judge them"

"They might think it is a bit uncool to have asthma because in quite a lot of films all of the geeks and nerds have asthma"

Some students also discussed how teenagers might feel embarrassed about using their inhalers in front of people who are not asthmatic. The students discussed how embarrassment can come when people do not know how to deal with an asthma exacerbation. For example:

> *"If they had shortness of breath and they used their reliever in front of someone who is not used to having asthma, they might think oh my gosh it's a big emergency and we've got to get everyone, because that happens a lot. People might think it is real, and you just need to take a puff of your asthma pump. But then they might feel embarrassed because loads of people are crowding around them when they only need to take a tiny bit because they are a bit short of breath"*

Some more positive comments were also coded, suggesting that there is no reason to feel embarrassed:

> *"I don't understand what they need to feel embarrassed about"*

> *"I don't think anyone should feel embarrassed to take it around other people because if you are friends with anybody, or if you want to be friends, then they are going to find out you have asthma"*

Using inhalers in public

The students identified reasons why teenagers may not use their inhaler in public, for reasons other than embarrassment. Again, the social impact was a key contributor, and the comments highlighted social concerns, including the perceived risk of being bullied:

> *"I think people might just say something unkind. People forget that you have asthma"*

> *"Some people deliberately don't take it because they feel scared because they don't want to tell people they have asthma or because they are scared about people teasing them"*

Some of the other comments implied that using an inhaler was a sign of weakness:

> *"Some people want to be cool in front of their friends, they might try and act cool, and so they won't take it to show that they are strong and can cope without it"*

Inconvenience

This was one of the more practical barriers. Using an inhaler regularly can be inconvenient, especially during other activities:

> *"Maybe they are going on a sleepover but they find there is no room in their suitcase so they just don't bring it"*

Complex treatment plans

This barrier highlighted the complexities of having multiple inhalers. Some teenagers do not realise they need different inhaler, or that their inhalers have different roles in asthma management. From the data, the blue SABA inhaler was used instead of the brown ICS preventer inhaler, possibly because there is an immediate benefit. The comments showed incorrect beliefs that the brown inhaler was not needed if the blue one had already been used, demonstrating a clear gap in knowledge:

> *"I don't use my brown one, I use the blue one"*

> *"They might think oh well if I have an asthma attack I could just use my blue one, there's no real point in using it"*

Excuse to miss class

Some of the students discussed concerns that teachers would view inhaler use as an excuse to miss class. There was also some evidence that children had previously used it as an excuse:

> *"I used to in primary school to get out of doing PE. I used to be no, I need to take my asthma pump, sorry I can't do PE"*

Fear of reliance

Some teenagers are reluctant to rely on medication, particularly when participating in sports or exercise:

"If you're running and you don't want to rely on an inhaler to have a long-distance run. They want to rely on themselves. That's why they won't take it"

One student also suggested that using an inhaler was counter-productive, especially during sporting activities:

"If I am using an inhaler it is basically giving me my breath back and that's not going to help. So, if I keep training and then it makes my lungs better without using it. So, I get used to it without using it, and so my lungs will get better"

No asthma symptoms

This barrier further highlighted gaps in knowledge about the role of medication in asthma management. The comments demonstrated a belief that inhalers were not needed as there were no active symptoms. This barrier is one example of accidental non-adherence:

"They might think that they won't really need it on that day so they just don't take it"

"I normally take the brown one when I am ill in the morning and every night, but I don't take it if I am not ill"

Inhaler efficacy

The students implied that some people do not believe that their inhaler is effective in managing the symptoms of asthma, and believe that the symptoms are better managed independently:

"I think they do not take it because they think they can control their asthma without it"

4.5.2 Theme Three: Communication

The comments that were coded under this theme demonstrated the challenges of discussing asthma, both socially and with healthcare professionals, and some of the comments identified how some of these challenges may contribute to non-attendance at routine appointments. Table twenty shows the sub-themes that were identified under this code.

Sub-Theme 1	Sub-Theme 2	Sample Quotation
Non-Asthmatics		
	Not taking asthma seriously	"Teachers don't take it seriously"
	Not being listened to	"You feel like no one is listening to you"
	Reluctance to talk	"It is frustrating to explain to someone who doesn't understand"
Healthcare Professionals		
	Trust in care	"My GP is pathetic"
	Language barriers	"They talk in doctor speak"
	ACT scores	"They would know how they can help you more"
Undiagnosed Cases		
	Barriers to diagnosis	"They don't want to tell themselves that they might have asthma"

Table 20. Communication sub-themes

Non-Asthmatics

There was a feeling among the students that some people do not take asthma seriously. The students spoke about teacher and/or sports instructors specifically, and discussed how they sometimes feel like they are not being listened to. Some of the comments also implied that some teachers and instructors are naïve about the potential seriousness of the situation. For example:

> *"Teachers do not take it seriously, they're like oh just control it"*
>
> *"It means that when you are actually having an asthma attack, or when it is really serious, people are likely yeah funny, and teachers as well"*

There was also an agreement that some peers without asthma can treat it as a joke, and do not recognise the potential seriousness of it. For example:

> *"Sometimes when you are taking a pump all of your friends they are like oh let's have a taste, and then try and take it off you and just play around with it. They don't understand that there is a reason why you've got an asthma pump. They just think it's a cool gimmick to have. Then they try and mess around with it whenever you need it and they think it is a fun thing to play with"*

There was a belief that people without asthma are not able to recognise the symptoms, and some of the students felt that this could be due to denial about the potential seriousness of the condition, which can make communication difficult:

"Sometimes if you have an actual asthma attack, people don't want to tell themselves that if there is someone trying to help you and they don't want to tell themselves that you're having an asthma attack, sometimes they say oh no you're probably just having a panic attack, you don't drink enough water. They just don't really want to face it and say that you are having an asthma attack"

It was also suggested that some people without asthma may not be interested in learning more about it. There was a belief too that awareness in schools may be limited, as asthma is not often talked about:

"It wouldn't be a conversation many people would have with their friends, because they don't want to and they don't feel comfortable talking to their friends about their health"

In response to this, the students felt that some people with asthma are reluctant to talk about it for a fear of being ridiculed:

"They might still laugh through knowing about it, like ha you're the one with asthma and we are not, they are different to us"

Some positive insights also emerged and highlighted that some people can be understanding, which can take the pressure off during an emergency:

"I don't think they would have a conversation about it, but they would understand. When you're a teenager, you'd understand what other people are going through"

Healthcare Professionals

The trust in the level of care that is often received by GP's was an important conversation point. Some students commented that their GP did not explain things fully during the initial consultation about their diagnosis and treatment:

"I don't think my GP has ever sat me down and said this is what you have"

"If my doctor says do this, or I'm going to give you this injection, they don't ask us what it is or anything"

However, it is unclear how often these students saw their GP, and how long ago they were diagnosed. There was also a suggestion that adherence would be improved if GP's spent more time discussing the implications and potential consequences of poor adherence. For example:

> *"If they told me what would happen if I don't take it, like it will result in an asthma attack, or maybe more serious stuff, I would definitely wake up in the morning if I had to"*

Seeing a different GP at each visit was also highlighted as a key unmet need among teenagers, and demonstrated a lack of continuity in care, which undermined consistent care:

> *"All the doctors say slightly different things and it is so confusing because I never see the same GP every time and then you just can't know"*

Some of the students also questioned whether their GP took their asthma seriously enough:

> *"I know my GP is pretty pathetic. I'll say I feel my asthma is getting worse and ask for a new inhaler and he will be like oh just keep using your regular or reliever inhaler, you will be fine"*

Notably, there was a resounding agreement that ACT scores should be reported back to GPs to improve the level of care that is received.

Undiagnosed Cases

Although the comments regarding communication with people who do not have asthma were limited, the response from the students indicated that it was important to acknowledge the concerns around being diagnosed, and highlighted the need to raise awareness of asthma. The students discussed some of the reasons why some people may delay visiting the GP with symptoms, primarily due to an underlying fear of not being taken seriously.

4.5.4 Theme Four: Knowledge

Gaps in knowledge were an important part of the discussion, with many of the comments demonstrating a lack of knowledge around asthma management. The students also agreed that improvements in knowledge would be beneficial in encouraging better management of asthma.

Although the literature is mixed, the comments here suggested that improved knowledge of asthma could improve self-management behaviours. Table twenty-one highlights all the knowledge areas that were noted by the students as needing improvement.

Sub-Theme	Sample Quotation
General information	"We don't know how to explain it"
Causes	"I don't know what causes it"
Medication	"I don't know what my pumps do"
Preventing Exacerbations	"How to prevent an asthma attack"
Side-effects	"What are the side-effects"

Table 21. Knowledge sub-themes

General knowledge

General knowledge about asthma was the most common area in which the students felt they wanted to improve their awareness. The students believed they knew a bit about asthma, but not as much as they should do, particularly regarding the physiology of asthma:

> *"The actual medical side behind it, because I don't think my GP has ever sat me down and said this is what you have"*

There was also a feeling that young people should know more about their condition, particularly when trying to talk about it with other people who do not have asthma. For example:

> *"For someone who has asthma, and for other people, they need to gain an awareness of people with asthma and how they are feeling"*

Some of the other areas of general knowledge that emerged from the comments were how asthma affects people during exercise and everyday activities, such as eating.

Many of the students agreed that if they knew more about asthma, it would help them live with their condition more effectively, and they would be able to manage it better. The students also agreed that people without asthma should learn more about asthma, as it is extremely common:

> *"I think you should know more about asthma, then you know how important it is to take it. I know quite a lot, when my doctor gives me a brown inhaler I know that I need to take it and that I can't really miss out because he wouldn't have given it to me if I didn't need it. I think it is really important to know quite a bit, because if you have asthma then you should really know everything there is to know about it"*

Causes

The causes of asthma were also highlighted as an area in which the students felt knowledge could be improved. For example:

> *"What causes your airways to be smaller than other people's?"*

Improvements in asthma medication, particularly why people need medication and why it helps to relieve the symptoms of asthma, were highlighted as a second area in which knowledge could be improved:

> *"What happens when we take the inhaler?"*

Medication

The students agreed that if understanding of the roles of different medication was improved, adherence to medication would also be improved.

Preventing exacerbations

Many students wanted to learn more about how to prevent an asthma exacerbation, as well as how to help other people if they see someone else have an asthma attack:.

> *"If you, or someone else, is having an asthma attack but they don't have their asthma pump. Obviously they won't be able to medically or professionally help them, but how to maybe calm people down, or make them breathe easier"*

Side-effects

An awareness of the sided-effects may help asthmatics to familiarise themselves with what is normal after taking medication, and what should be discussed with their doctor during their asthma review. It may also help to reduce the high threshold that many young people seem to have regarding the severity of asthma symptoms, and when to seek medical assistance.

4.5.5 Theme Five: Social Impact

The sub-themes that were analysed under this code are shown in table twenty-two.

Sub-Theme	Sample Quotation
Peer awareness	"People that don't have asthma don't know how you feel"
Stigma	"They feel if you've got asthma you shouldn't take part"

Table 22. Social impact sub-themes

Peer awareness

The comments indicated a feeling of frustration among the students about how it feels when the people around them do not understand asthma and how it is managed:

> *"You start crying because you are frustrated and you are angry and it is just the worst feeling because they don't understand that you're struggling to breathe, you're struggling to talk"*

Some of the students also discussed some of the negative reactions from other people that have been encountered when someone is having an asthma attack. The general consensus was that people do not know what to do:

> *"There are two extremes. Sometimes people are unsympathetic and other times they panic and it's like, well neither is helping me at all really"*

Although peer awareness was considered important in helping to manage asthma more effectively, it was felt that raising awareness would not be effective, due to a lack of engagement from people who are not directly affected by asthma. However, there was agreement that people without asthma lack an awareness, and therefore it can be difficult to talk about:

> *"They might not understand. I think it is better to talk to someone who has asthma"*

> *"Some people, they will react in a supportive way, like friends, but then some people they might make fun of it and use it as your weakness as their strength"*

Conversely, some students felt that raising awareness among peers would be reassuring, in case of an asthma attack:

"I like to let people around me aware of it because if I start to cry or something, that's when my asthma and my chest gets tight and stuff, and so if people around me are aware of it then obviously it is easier for me to access my pump"

While it may not be deliberate, some of the students discussed how people with asthma can be treated differently because of their condition:

"Sometimes people try and patronise you and they're like oh, it's ok. Sometimes if you're just hanging out with people normally, then they talk to you normally, but if you start taking your asthma pump then sometimes people start patronising you and just trying to, and they're trying to be nice, but they don't really understand that it is just a bad medical condition, but I am still the same person"

Stigma

There was a misperception regarding the extent to which people with asthma should participate in sports. For example:

"I feel that if you've got asthma and you are swimming, they feel that if you've got asthma you shouldn't be taking part in so many activities. They think that you are the average person and you think that they are right because of your health you shouldn't go swimming or do any activities, just watch people doing stuff instead"

4.6 Discussion

In total, six focus groups were conducted across four London secondary schools, and 58 students with asthma participated. The aim of the focus groups was to understand more about the barriers to adherence among teenagers with asthma, and ascertain how teenagers characterise poor asthma control. Thematic framework analysis was applied to the 397 comments that were collected, and these were coded into five themes:

i. Asthma
ii. Medication adherence
iii. Communication

iv. Knowledge

v. Social impact

Data coded under the asthma theme suggested disconnect between perceived asthma control and actual asthma control. Compatible with previous literature, for example the Room to Breathe survey by Carroll *et al* [74], the children surveyed by me showed evidence of high thresholds for poor asthma control, with many students indicating that poorly controlled asthma is characterised by day-long wheezing and an inability to carry out simple activities, such as climbing stairs. Very few students could correctly identify the characteristics of poorly controlled and well controlled asthma. Although many of the students did recognise that poorly controlled asthma could lead to sleep disturbances, as discussed in the GINA guidelines [2], the severity of the night-time awakenings were more extreme than the GINA guidelines would suggest, with some students believing that night-time awakenings would occur every night and would not stop. Similarly, according to some of the comments, some children believed that even well controlled asthma might still require the use of a reliever inhaler to control the symptoms of asthma, and some children believed that asthma was well controlled even when symptoms were present, as it meant they were using their inhalers. This not only demonstrates inadequate awareness of the role of different medication, but also indicates that inappropriate management strategies may currently exist. None of the children discussed medication use as a management strategy to prevent future asthma attacks. This reflects the findings by McQuaid *et al* [161]who also found that medication use as a prevention strategy was less commonly reported than medication use in response to asthma symptoms only.

The second theme was medication adherence. My earlier questionnaire data highlighted low levels of adherence with medication among children, and many of the free-text responses suggested that this behaviour was deliberate, rather than accidental. Some of the unintentional barriers to adherence, for example forgetfulness, were not discussed as widely as the more intentional non-adherent behaviours. Much of the discussion within these theme referred to social concerns (e.g. embarrassment or a fear of being bullied), as well as incorrect beliefs regarding the efficacy of the medication. Adherence with asthma medication has been widely researched, and the findings from these focus group largely mirror those in the literature. For example, Horne,

2006 [9], highlighted patient beliefs and unpleasant side-effects as common reasons for non-adherence.

The findings from my focus groups did also show that some children may be unaware that they are not adhering to their treatment plan, and may genuinely believe that they are acting with the best intentions. For example, although failing to use medication due to an absence of symptoms is considered intentional nonadherence, the children may believe that this is the correct course of action and may therefore be unaware that their behaviours are not adherent. This could also explain why the questionnaire data showed a discrepancy in adherence scores; the number of children who claimed to be deliberately not taking their medication was much lower than those who were not adherent with their medication due to forgetfulness, however the free-text responses demonstrated more intentional reasons for non-adherence.

The third theme to emerge was communication with healthcare professionals and their peers. Communication with healthcare professionals was a key unmet need of the children, and many of them expressed concerns over a lack of continuity with care, and seeing a different GP or nurse at each appointment, which could undermine the care that a child is receiving. This highlights the importance of having a clear asthma action plan, which can be brought to each medical appointment, and will inform a doctor of the current management plan, even if the usual GP is unavailable. The BTS guidelines emphasise the importance of a written action plan to be included alongside self-management strategies, to achieve better outcomes [162], however the National Review of Asthma Deaths [14] evidenced a distinct lack of asthma action plans among children who had a death from asthma. Communication with peers was also important to the children, particularly in raising awareness of asthma in schools. However, there were mixed views about whether raising awareness among peers would be beneficial or not. While some children felt that it would be helpful to raise awareness in schools, so that peers and teachers know how to respond to an asthma attack, others were concerned that peers would not be interested, and it may trigger bullying. This is something that will be addressed in a future school-based self-management intervention, to be piloted in London secondary schools.

Another theme to emerge was knowledge of asthma. The literature on the role of knowledge in improving asthma management behaviours is mixed, however the findings from my earlier

questionnaire showed low levels of knowledge regarding the role of the ICS ± LABA inhaler. The students in the focus groups agreed that they could know more, and felt that improved knowledge would lead to improved medication adherence among teenagers. The main gaps in knowledge included the causes of asthma and the role of different medications in managing asthma symptoms. Although knowledge alone may not be sufficient to change behaviour, and attitudes may be more influential in changing healthy behaviours, there was agreement that if young people were aware of why they needed to take their medication, particularly their ICS ± LABA medication, then they would be more inclined to use it properly. Ho *et al* 2003 [125] previously found no sufficient evidence to suggest that knowledge directly improves adherence, although concluded that there could be an indirect causal link that should be addressed further. It could also be that instead of addressing knowledge alone as the key to improving adherence, attitudes should also be considered. These focus groups also give a clearer understanding of where some of the gaps in knowledge are among teenagers with asthma in London, and what areas of asthma management future self-management interventions should target.

The final theme to emerge from the data was the social impact of asthma. Many of the comments here highlighted a lack of awareness among people without asthma, and the way that young people feel they are treated when they try to participate in sport, or when they have an asthma attack. In accordance with the findings of the questionnaire, peer attitudes are important in asthma management behaviours among teenagers, and could be some of the biggest drivers behind medication adherence. The findings from the questionnaire showed that a small number of children had been bullied due to their asthma (14%), however this was a fear that was expressed by almost all of the students, despite less than a fifth indicating that this was something they had experienced in the earlier questionnaire. It could be that the perception among children with asthma is different to the behaviours of their peers without asthma, and this is something that should be addressed in future research.

There have been a number of studies to date which have used qualitative methods to assess barriers to adherence in asthmatic children, and the findings from these focus groups are largely in accordance with those previously reported [102]. Previous studies have also focused on family/caregiver influences as a barrier to adherence in children and adolescents [102, 113],

however these were not explored under the current framework. The findings from these focus groups will be used in conjunction with the questionnaire data presented in chapter three, and the outcomes of the systematic review in chapter five, to inform a future self-management intervention.

These focus groups also included a number of limitations. First, the response rate from the schools was very low, and constituted 16.7% of the schools that participated in the questionnaire phase of the study. It could be that the schools that participated had an existing interest in asthma, therefore the generalisability of the findings is reduced. Similarly, as the students had previously participated in the questionnaire, it could be that they had some existing knowledge of the aims and objectives of the research, and therefore may have been giving responses that they felt were appropriate, rather than reflecting what they actually believed.

Second, due to constraints imposed by the REC regarding the discussion of personal information, the students were encouraged not to discuss their own experiences of asthma. While some students chose to divulge this information regardless, it is unclear whether any of the comments that were given were based on previous experience. This undermines one of the key advantages of focus groups in providing subjective data, as the discussions were all based on hypothetical situations.

Third, some of the views that were expressed, particularly experiences with teachers and healthcare professionals, were based on personal opinion and could not be validated. Future researchers may wish to explore the attitudes and beliefs of different groups of people involved in asthma treatment and care, including family members, friends and healthcare professionals, and compare it with the attitudes and beliefs of young people with asthma. A discrepancy may exist between how children with asthma believe they are perceived, and the way they are perceived in reality by different people, which could contribute to adherence and self-management behaviours.

Fourth, formal analysis of the data was no conducted, instead a 'light-touch' approach was used. This method of analysis was based on previous literature, and my previous experience of qualitative research. The analysis methods described in this chapter follow the recommendations in the literature [160], and were checked with a Health Psychologist, experienced in qualitative research, for completeness. However, the initial analysis was carried out by largely quantitative

researchers, and therefore the analysis may be limited in reliability of the findings. The reason this data was analysed in this way was to clarify the findings from the questionnaire study, which answered the primary research objective, and to inform the development of a future self-management intervention.

4.6.1 Justification for Methodology

The focus groups collected subjective data on a number of topics relating to the management of asthma in young people. The objectives of the focus groups (highlighted earlier in this chapter) could be addressed primarily using subjective data, therefore either focus groups or individual interviews were considered the most appropriate methodology. Focus groups were subsequently selected above interviews and quantitatively equivalent methods for several reasons.

The aims of the focus groups were to further understand the barriers to adherence among teenagers with asthma, as well as identify their understanding of good and poor asthma control. Although focus groups and interviews both offer insights in behaviours and experience, and allow the researcher to observe non-verbal responses, such as emotions, and facial expressions, focus groups have the added advantage of observing responses to comments from other members of the group. The students in the focus groups shared a mutual diagnosis of asthma, however the severity and experiences were different for each student. The interactive nature of the focus group enabled the students to respond to each other both verbally and non-verbally, and use responses from other people to spark conversations that may have otherwise not occurred in individual interviews. The focus groups also enabled the students to reflect on the opinions of others in the group and compare them with their own opinions and experiences.

Although interviews typically lack the conversational nature of a focus group, and there is no opportunity to build a discussion with other people, they do enable a more professional relationship to develop between the interviewer and the participant, which is rarely seen during a focus group as the facilitator is often less involved in the discussion. This enables a relationship to develop between the interviewer and the participant, which potentially reassures the participant and develops their confidence to discuss certain topics. Despite this, interviews do not allow the conversation to deviate away from the pre-defined interview question, even if the interview

appears to take an alternative path. One benefit of this is that it gives the interviewer more control over the discussion topic, and therefore ensures that all of the data that is collected is relevant to the research question [163]. The structured nature of interviews also allows the data to be aggregated and analysed more easily, compared with semi-structured interviews and focus groups. Although semi-structured interviews offer the flexibility of a focus group, and encourage participants to elaborate on their responses, the lack of structure often means that it is difficult to compare and code responses from all individuals.

There is also an added risk with focus groups that the students may not express their honest views on a topic, for fear of deviating from the social norm. During the focus groups, the facilitators tried to account for this by running an ice-breaker game in the beginning, to help the students get to know each other and feel more comfortable in their surroundings. The focus groups were also held in school, therefore the students were familiar with the environment, and may have recognised a few of the other students participating in the group. The students were also reminded to keep all discussions confidential, and not to repeat anything outside of the focus group.

A clear advantage of focus groups is the ability to collect large amounts of data from a larger number of children than interviews would allow, therefore making them more costly and time efficient. In this way, the quality of the data could also be richer, as there are more opinions and comments to code during the analysis.

4.6.2 Overall Conclusions

The primary aim of the focus groups was to further understand the barriers to adherence among teenagers, following the outcomes of the questionnaire data. Thematic framework analysis was used to analyse the comments, and two independent researchers coded and analysed each transcript, before the coding framework was developed. The comments from the focus groups demonstrated a number of unmet needs among children and young people with asthma, such as inadequate communication with healthcare professionals and peers, and a number of barriers to adherence that need to be addressed. The students desire to learn more about asthma, and to raise awareness in schools about asthma also highlights key limitations in current self-management

strategies that could be addressed in a future school-based intervention, which will be further discussed in chapter six.

Some notable limitations have arisen from this part of my thesis, however despite these limitations, the findings discussed here contribute towards understanding the reasons behind non-adherence among teenagers in London with asthma, and the ways in which these barriers can be addressed. The focus groups have further supported the findings from the questionnaire study, and further highlight the importance of the school environment as a space to consider for future research.

Plain Language Summary

The primary aim of the focus groups was to further understand some of the barriers to medication adherence among children and young people, given the high levels of non-adherence that came out of the questionnaire data. A total of six focus groups were conducted in four secondary schools, and 58 children took part. The comments were analysed qualitatively using thematic framework analysis, and five themes came out of the data.

The most commonly coded theme was asthma. This included opinions of asthma, as well as the children's understanding of poor asthma control. There was a difference between their understanding of poor asthma control, compared with the clinical explanation, and a higher barrier to experiencing symptoms was seen, before considering asthma to be poorly controlled.

The second theme was medication adherence. Similar to the free-text data from the questionnaire, the most commonly reported barriers to adherence included forgetfulness, incorrect beliefs about the medication, and social concerns. There was a real concern among the children about using inhalers at school, in case they were bullied, or seen as weak.

The third theme was communication. Most of the comments here referred to communication with healthcare professionals, and seeing different doctors each time. Some students also showed concern that they did not understand the medical terminology that was sometimes used. Communication with people who do not have asthma was also important. Many children felt that awareness among people without asthma was low, and should be improved. However, some other children felt that unless someone has asthma, it would not be helpful to teach them about the condition.

The fourth theme was knowledge. Although the evidence for this is limited, the children all agreed that adherence to medication would be better if they had greater knowledge about their medication and why it was important. The general causes of asthma and what happens in the lungs was also an area in which the children thought knowledge should be improved.

The final theme was the social impact of asthma. From the adherence data it was clear that this was important in adherence behaviours. However, the children also discussed the reaction that is sometimes received when they use an inhaler in public, or have an asthma attack.

Chapter 5. School-based Self-Management Interventions for Children with Asthma

In this chapter, I perform a systematic review of school-based self-management interventions for children with asthma. This review uses a mixed-methods approach, and includes two components. The first component is a process evaluation, which seeks (change everything to present tense) to identify the factors of an intervention which are associated with successful implementation. This used Qualitative Comparative Analysis (QCA; discussed later in the chapter) to assess both quantitative and qualitative studies. Process evaluations can help to shape and strengthen future interventions, through using qualitative comparative analysis (QCA) to highlight the components of interventions that may be most important to their success. The second component was a meta-analysis of randomised controlled trials (RCTs), to identify if school-based self-management interventions for children with asthma are successful at improving children's outcomes, such as hospitalisations and quality of life. A mixed-methods approach to this review contributes to the literature both empirically and methodologically. First, it will help in improving understanding of both the processes involved in implementing an intervention, and whether school-based self-management interventions for children with asthma are effective. The findings from the QCA generated hypotheses regarding whether interventions are effective, and how they should be implemented in the future, which were later tested in the meta-analyses. Second, the results of this review will directly inform the development of a school-based self-management intervention, to be tested in a London-based feasibility study; the results of this review will directly inform the intervention design.

5.1 Background

Although asthma is the most common chronic condition in children in the UK, the risk of developing asthma is not the same for all children. Instead, there are several characteristics which are thought to contribute to the overall risk of the disease. For example, in the UK, children from White and Black ethnic backgrounds are at higher risk of developing asthma, compared with children from South Asian backgrounds [150]; and within these groups further variations have been identified. For example, although children from South Asian populations are at a lower risk of developing asthma, their risk of being admitted to hospital following a complication from

asthma is greater. Children from black backgrounds are also at increased risk of hospitalisation due to asthma, compared with children from white ethnicities. Socioeconomic status has also been shown to be associated with health outcomes. For example, the risk of developing asthma is thought to be higher among children from low-income families living in the UK.

The main purpose of this systematic review is to evaluate the evidence on school-based self-management interventions for children with asthma. As discussed in chapter two, self-management is the process of educating patients and enabling them to control their asthma symptoms away from the clinical environment, and reduce the risk of future exacerbations [79]. According to the BTS, self-management is defined as "the tasks that individuals must undertake to live with chronic conditions, including having the confidence to deal with medical management, role management and emotional management of their conditions" [162]. In terms of asthma, this includes good inhaler technique and being able to recognise and respond to the symptoms of asthma. For this systematic review, self-management studies were only included if they included education on asthma alone. The focus was on studies that were delivered in schools as it is a familiar learning environment for children. The focus on the school is also encouraged by advisory groups to UK policymakers, who view the integration of health, educational and social care services as important in improving the quality of life of children with chronic conditions such as asthma, and in reducing differences in outcomes such as school attendance [93].

Although previous literature has shown that school-based self-management interventions for asthma are successful in improving some health-related outcomes, including reducing rates of unscheduled care and school absences, no systematic review to date has tested the effectiveness of schools as a potential space for delivering interventions [164].

Some school-based self-management intervention components that may be important are shown in the logic model in figure 19. The logic model, developed by the review authors, shows the outcomes of interest within this review, and how these outcomes fit within the review objectives. The logic model was developed on the basis of published literature and systematic reviews, and by establishing the outcomes of interest from school-based self-management interventions and working backwards to highlight the causal chain necessary to achieve these outcomes. Using a

logic model in this way helps to identify the types of data that may be needed to gain an understanding of the different intervention components and implementation processes [165]. This matches the objectives of the review in terms of identifying both the impact of school-based asthma interventions and the components associated with change and impact. The intervention implementation outcomes are shown in figure 19 as 'process metrics'. The 'action' part of the model included the external school context, and inputs already in place to run the intervention. The 'change' part of the model shows the stages of change and processes necessary to reach the intended outcomes.

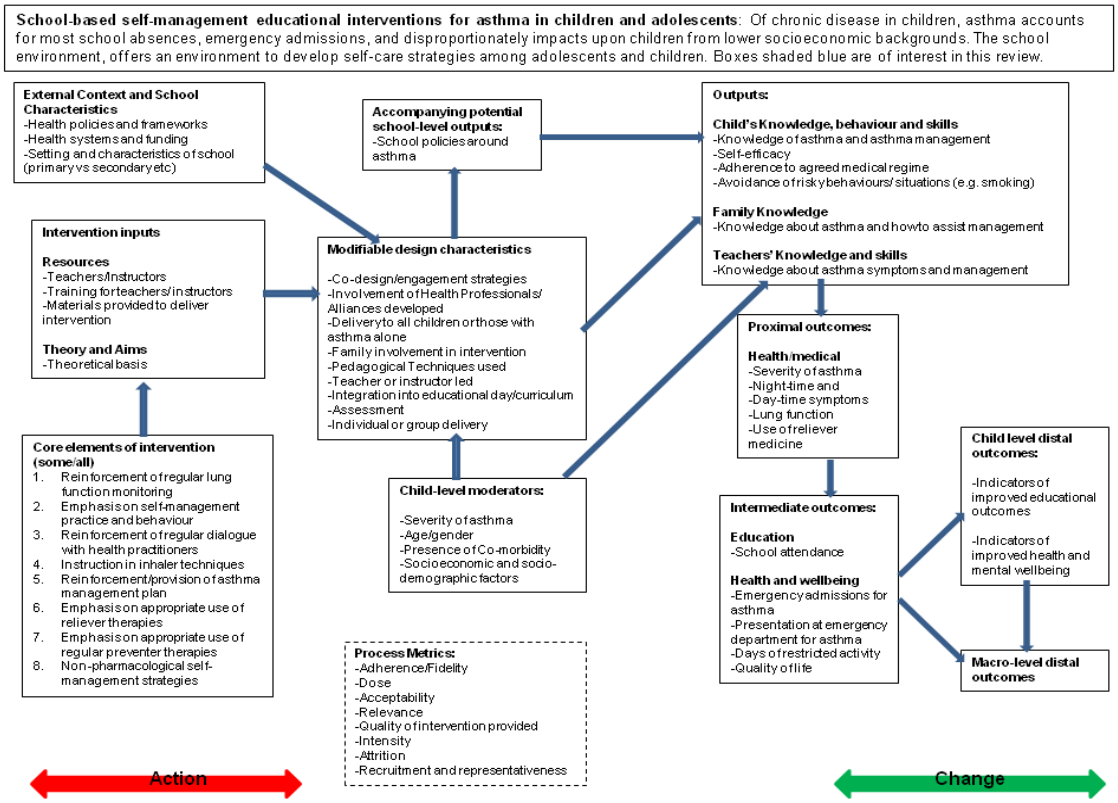


Figure 19. Logic Model

Previous reviews of paediatric asthma self-management interventions, for example by Guevara *et al* 2003, have shown improvements in lung function, school absenteeism, emergency hospital visits, and patient self-efficacy [166]. A separate review by Boyd *et al* also found that targeted interventions can lead to improvements in hospital admissions among those who are most at risk of hospitalisation [167]. While many reviews have suggested that educational interventions that are delivered to children with asthma can be effective, these reviews have largely included

interventions which have been delivered in the school, as well as in the home and clinical environments [168, 169]. Recognising this, Welsh *et al* has highlighted that no widespread agreement currently exists on the most effective setting for delivering asthma interventions to children [170]. To date, two systematic reviews have evaluated the evidence for interventions delivered exclusively within the school environment. Both reviews found that school-based interventions improved school absences, however the evidence showing the effectiveness of these interventions on other outcomes, such as hospitalisations, was limited [83, 94]. A third review, conducted by Al Aloola *et al* also examined the effect of a school-based intervention on children's outcomes, however this review considered studies that involved primary school aged children only [164].

To date, few reviews have included an analysis of 'process-level' measures, such as changes in school policy. One exception to this is a review by Pinnock *et al* [171], which assessed how asthma self-management interventions should be implemented, however this did not focus on schools alone. Nonetheless, an analysis from two studies conducted in schools showed that high school turnover and a lack of parental involvement could be challenges to implementation. An analysis of such process level factors would further highlight the components of interventions that may be most important in understanding the success of an intervention.

In this review, the aim was to combine the evidence of school-based self-management interventions for children with asthma, for the first time, using a mixed-methods approach. Although other reviews have aimed to include a mixed-methods approach [172, 173], this review sought to include both meta-analyses of quantitative studies, and qualitative studies. The process evaluation data was analysed using Qualitative Comparative Analysis (QCA).

5.2 Objectives

This review has two primary objectives:

1. To identify the intervention components and processes that are associated with successful intervention implementation
2. To assess the effectiveness of school-based interventions for the improvement of asthma self-management on children's outcomes

The first objective will be addressed using Qualitative Comparative Analysis (QCA; described later in the chapter) of process evaluation studies, to identify the combination of intervention components and processes that are associated with successful implementation. This approach aims to highlight the extent to which an overlap exists between a set of studies that are successful in their implementation and sets of studies that share different combinations of intervention characteristics.

The second objective will be addressed through conducting meta-analyses of outcomes collected within RCT studies. The link between how well interventions are implemented and their effectiveness is explored in separate models, as well as through undertaking additional subgroup analyses.

5.3 Methods

5.3.1 Criteria for considering studies for this review

Identifying process evaluation studies

Process evaluation studies seek to explore the implementation, receipt, and setting of an intervention, and assess whether an intervention was delivered the way it was intended [174]. QCA is currently a novel technique in systematic reviewing, however it is steadily gaining more interest from researchers due to how it addresses the weaknesses in correlational/associational analyses. For example, correlational approaches test for the success and failures of covariates simultaneously, and cannot identify the importance of a single component in an intervention, due

to a small number of available studies [175]. This means that some of the reasoning for why a certain condition did not occur in an intervention may be lost in correlational analyses. Moreover, QCA does not need to assume linear effects. Instead, it can understand that a particular condition may be associated with both positive and negative outcomes, depending on context and the presence or absence of other conditions.

The terms "process" and "qualitative" are often used interchangeably, however data for a process evaluation can be either quantitative and qualitative [176]. Although there is no 'gold-standard' definition of what a process evaluation is, they can be used to develop theories around how interventions works. The Medical Research Council (MRC) [177] provide some guidance on how to conduct process evaluations, and recommend that the core components of a process evaluation include:

i. A clear description (and evaluation) of the implementation and processes of intervention implementation
ii. A clear analysis of mechanism of impact (participant responses to and interactions with the intervention)
iii. A clear description of the context and analysis of how contextual factors affect mechanisms and implementation

For the purposes of this systematic review, process evaluations were considered to involve systematic measurements to determine the extent to which an intervention was implemented as planned, following the guidance from the MRC. Implementation measures focused on fidelity, attrition, adherence and dosage, and process evaluation studies were identified as:

i. A study that was self-defined as a process evaluation, or;
ii. A study that included the elements of a process evaluation in a defined section of an outcome evaluation, or;
iii. A study where process evaluation data were integrated within an outcome evaluation, but where measures around processes were detailed and extractable within the results

Where studies did not directly identify themselves as a process evaluation, they must have contained the following components:

i. An assessment of core components (implementation, mechanisms, context)

ii. Clear research questions guiding the process evaluation

iii. Use of recognised evaluation methods (described by Moore *et al* [177])

Studies were also included if they had a focus on the presence/development of school asthma policies, and this was later extended to studies measuring broader school-level commitment (e.g. teacher involvement).

Previous systematic reviews of process evaluation studies have often only included process evaluation studies linked to an outcome evaluation [178]. In this review, some process evaluation studies were linked to RCTs that assessed the effectiveness of an intervention, but studies were also included that evaluated the implementation of several study designs, if they met the other inclusion criteria. This allowed the process evaluation data to contribute towards theory development, tested within a mixed-method framework.

Identifying outcome evaluation studies

To measure the effectiveness of interventions on children's outcomes (to achieve the second review objective), studies were included if they comprised a randomised parallel group design, involving randomisation at either the individual or school level (cluster-randomised trials).

Publication date and language

Exclusion criteria were applied to the date in which studies were published, to help ensure that the content of the self-management interventions were relevant to current recommendations. Recommendations on self-management practices were first developed in the UK in 1990, based on publications in the British Medical Journal and Archives of Diseases in Child Health [179]. These recommendations were also developed in the USA around the same time [180], and were published in the GINA guidelines soon after. Considering this, studies were only included if they were published from 1995 onwards, to correspond with the publication of the first GINA guidelines. Studies were also only included if they were published in English. The potential impact of this restriction was assessed through conducting explorations of the impact of publication bias.

Types of participants

Participants included school-aged children and young people (5-18 years old) with asthma, who participated in the intervention within their school. If the intervention included young people and adults (e.g. in a further education college), these studies were only included if most of the participants were aged 18 years or younger. Interventions were also included if they delivered some components to peers, teachers, and/or guardians/families, however only where they involved at least partial delivery of the intervention to school-aged participants with asthma within the school environment. No criteria were imposed over the type of educational institutions that were included in the review, as long as it represented the location where participants received most of their education.

Types of interventions

Interventions were selected that aimed to develop and improve self-management of asthma among children through at least one of the following:

i. Increasing knowledge of asthma and it's self-management
ii. Enhancing self-management skills
iii. Improving self-management behaviours and practice

Among studies that sought to improve asthma self-management, the intervention was only included if it involved teaching at least one aspect of self-management, as outlined below:

i. Reinforcement of regular monitoring of lung function
ii. Emphasis on the importance of self-management practice and behaviour
iii. Development of a partnership/alliance between patient and primary care/healthcare practitioners (including school nursing staff) for the management of asthma
iv. Instruction on inhaler technique
v. Reinforcement/provision of an individualised written asthma management plan
vi. Emphasis on the importance and appropriate use of reliever therapies such as $beta_2$-agonists (SABA) [16]

vii. Emphasis on the importance and appropriate use of regular preventer therapies such as inhaled corticosteroids (ICS) and combination inhaled corticosteroid and long-acting beta$_2$-agonist therapies [16]

viii. Non-pharmacological self-management strategies focused on avoiding or reducing the risk of experiencing asthma or asthma attacks, including lifestyle and behavioural modifications [16]

Interventions could also focus on changing asthma management within schools, for example by changing school policies. However, these studies were only eligible if they also included the development and evaluation of asthma self-management behaviours and skills among children. No criteria were applied to the intervention facilitator. Instead, the intervention could be delivered by a trained educator, nurse, doctor, peer, or social worker, or a combination of these.

Comparison

For the outcome evaluation studies, the comparison groups were either usual care or an intervention that did not focus on asthma. For the process evaluation studies, the comparison group could have received another asthma intervention, or studies may not have included a comparison group at all.

5.3.2 Types of Outcome Measures

Outcomes for meta-analyses

The primary outcomes were based on those identified by the BTS as indicators of good asthma control [16]:

i. Asthma symptoms or exacerbations leading to admission to hospital (children with one or more admissions or admission rates)

ii. Asthma symptoms or exacerbations leading to emergency hospital visits

iii. Parent-reported absence from school

iv. Days of restricted activity

There were also several secondary outcomes of interest:

i. Unplanned visit to hospital or GP due to asthma symptoms

ii. Experience of day and night-time symptoms

iii. Lung function

iv. Use of reliever therapies such as $beta_2$-agonists

v. Corticosteroid dosage and/or adherence to add-on therapies

vi. Health-related quality of life (HRQoL) as measured by a validated questionnaire

vii. Study withdrawal

Outcomes for QCA: Defining a successful intervention

QCA is a method of analysis that develops understanding of which combinations of intervention components and processes trigger successful outcomes. QCA is based on set theory, and explores the degree of overlap between a set of successfully implemented studies, and a set of studies with a particular range of intervention components and processes.

The first step in the QCA used in this review was to identify 'successful' implementation studies. Currently, there is no standardised approach to assessing whether an intervention is 'successful' or not [181]. Instead, several steps were followed, in accordance with the literature. First, the features of intervention implementation that were related to intervention fidelity were examined, as well as the evidence around attrition, dosage and adherence. A literature review of implementation scoring methods in public health interventions [181] included one study by Rosecrans *et al* that examined the implementation of a complex intervention that included a school component [182], which subsequently formed the basis of the coding scheme within this review. The authors here used the following criteria: low implementation (0-49%); moderate implementation (50-74%); or high implementation (75-100%)' [182]. The 75% or above threshold also corresponds with the 25% attrition rate that is often incorporated within study sample size calculations for public health trials involving children, and indicated a high implementation score, and was considered to be a 'successful' intervention.

For each of these indicators above, a combination of direct and transformational assignment was used to set values (shown in table 23). Numerical values were assigned to qualitative data, and all the data was adjusted using transformational assignment. In doing this, all of the qualitative and

quantitative data could be combined into a single measure. The data was combined by totalling each value and standardising the total score.

	Field	Instructions for extractors	Coding values and method
		Setting and Participants	
1	No. of children	Record total number of children involved in intervention	Transformational assignment: Interventions with 15 or fewer children = 0; Interventions with 90 children = 0.5; Interventions with 300 or more children = 1
2	Multiple settings	Evidence if delivered at more than one school	Direct assignment: Yes = 1; No = 0
3	Single sex school	Evidence if delivered in a single sex school	Direct assignment: Yes = 1; No = 0
4	Type of school	High school; Primary/Elementary; Junior/Middle; Other	Direct assignment: High school = 1; Middle/Junior = 0.66; Elementary/Primary = 0.33; Missing = 0.5; Mixture of high and middle schools = 0.75
5	Ethnicity of children	Whether minority ethnic children are targeted	Transformational assignment: Interventions with 25% or fewer children from ethnic minority = 0; Interventions with 33.3% from ethnic minority = 0.5; Interventions with 50% or more from ethnic minority = 1. Where there is missing values, assume not targeted (0.25)
6	SES of children	Where children from lower SES groups targeted? Indicators: Parents with low levels of education; low household income; receipt of free school meals	Transformational assignment: Interventions with 25% or fewer children from low SES groups = 0; Interventions with 33.3% of children from low SES group = 0.5; Interventions with 50% or more children from low SES group = 1. Where there is missing values, assume not targeted (0.25)
7	Child age	Age group/classes targeted: age 5-10	Direct assignment: Yes = 1; No = 0
		Age group/classes targeted: age 11-14	Direct assignment: Yes = 1; No = 0
		Age group/classes targeted: age 15-18	Direct assignment: Yes = 1; No = 0
8	Direct recipients	Children	Direct assignment: Yes = 1; No = 0
		Teachers	Direct assignment: Yes = 1; No = 0
		Parents	Direct assignment: Yes = 1; No = 0
		School nurse	Direct assignment: Yes = 1; No = 0
		Programme Design	
9	Theory driven	Does the study name a theoretical framework which underpins the intervention design or delivery style	Direct assignment: Yes = 1; No = 0
10	Intensity of the programme	High intensity = 6+ sessions; Medium = 3-5 sessions; Low = 1-2 sessions; Unclear. Variable transformed to reflect whether the	Direct assignment: High intensity = 1; Medium = 0.66; Low = 0.33. Where no evidence, this was coded as 0.33

		intervention was of a high intensity	
11	Personalisation/Tailoring	Did the programme include individual sessions or use personalisation in any way to alter curriculum to individual students' needs	Direct assignment: All sessions personalised = 1; Some sessions personalised = 0.66; Minor component personalised = 0.5; No evidence = 0. This is personalised by or individual sessions with an instructor; self-study components no included here
12	Timing of the intervention	Does the intervention interfere with the child's free time?	Direct assignment: All sessions do = 1; Some sessions do = 0.75; Missing data = 0.5; Not interfering with free time = 0
		Does the intervention interfere with the child's lessons?	Direct assignment: All sessions do = 1; Some sessions do = 0.75; Missing data = 0.5; Not interfering with education = 0
13	Information about control condition	Whether trialists were also providing a control for the main intervention	Direct assignment: An equivalent control = 1; not an equivalent = 0.66; No control = 0
14	Instructor or facilitator	Teacher	Direct assignment: Main instructor = 1; Secondary instructor = 0.66; Not mentioned as an instructor = 0
		Peer	Direct assignment: Main instructor = 1; Secondary instructor = 0.66; Not mentioned as an instructor = 0
		School nurse	Direct assignment: Main instructor = 1; Secondary instructor = 0.66; Not mentioned as an instructor = 0
		Self-directed/child-directed	Direct assignment: Main instructor = 1; Secondary instructor = 0.66; Not mentioned as an instructor = 0
		Parent	Direct assignment: Main instructor = 1; Secondary instructor = 0.66; Not mentioned as an instructor = 0
		Other	Direct assignment: Main instructor = 1; Secondary instructor = 0.66; Not mentioned as an instructor = 0
Programme Content			
15	Curriculum	Lung physiology/asthma biology	Direct assignment: Yes = 1; No = 0
		Asthma acceptance	Direct assignment: Yes = 1; No = 0
		Symptom monitoring and medication use	Direct assignment: Yes = 1; No = 0
		Avoiding triggers	Direct assignment: Yes = 1; No = 0
		General health	Direct assignment: Yes = 1; No = 0
		Strengthening alliances	Direct assignment: Yes = 1; No = 0
		Focus on smoking	Direct assignment: Yes = 1; No = 0
		Personalised/tailored	Direct assignment: Yes = 1; No = 0
		School performance	Direct assignment: Yes = 1; No = 0
		Emergencies	Direct assignment: Yes = 1; No = 0
		Unknown	Direct assignment: Yes = 1; No = 0
		Focus on breathing techniques	Direct assignment: Yes = 1; No = 0
16	Learning styles	Problem solving component	Direct assignment: Yes = 1; No = 0
		Self-directed	Direct assignment: Yes = 1; No = 0
		Peer-delivery component	Direct assignment: Yes = 1; No = 0

		Interactive	Direct assignment: Yes = 1; = 0
		Didactic component	Direct assignment: Yes = 1; No = 0
		Other style/unclear	Direct assignment: Yes = 1; No = 0
17	Program ethos/aims	Emphasis on social benefit	Direct assignment: Yes = 1; No = 0
		Emphasis on improving wellbeing	Direct assignment: Yes = 1; No = 0
		Emphasis on having fun	Direct assignment: Yes = 1; No = 0
		Emphasis on fostering independence/personal responsibility	Direct assignment: Yes = 1; No = 0
		Emphasis on developing children's knowledge	Direct assignment: Yes = 1; No = 0
		Emphasis on collaboration	Direct assignment: Yes = 1; No = 0
		Emphasis on tailoring for specific group needs	Direct assignment: Yes = 1; No = 0
		Emphasis on breathing technique	Direct assignment: Yes = 1; No = 0
		Unclear	Direct assignment: Yes = 1; No = 0
18	Additional components on school asthma policy	Additional support provide for developing school policy	Direct assignment: Yes = 1; No = 0
		School asthma policy developed organically	Direct assignment: Yes = 1; No = 0
Additional processes undertaken – planned and unplanned			
19	Recruitment methods school	Ad hoc/convenience sample of schools	Direct assignment: Yes = 1; No = 0
		Census of school district	Direct assignment: Yes = 1; No = 0
		Unspecified methods of school recruitment	Direct assignment: Yes = 1; No = 0
20	Additional processes to improve/attenuate attrition/enrolment	Marketing materials sent to parents	Direct assignment: Yes = 1; No = 0
		Low motivation of students acknowledged	Direct assignment: Yes = 1; No = 0
		Incentives used (child or parent)	Direct assignment: Yes = 1; No = 0 Incentives for teachers and no evidence for children/teachers = 0.5
		Make-up/catch-up sessions provided	Direct assignment: Yes = 1; No = 0
		Reminders sent to parents/children	Direct assignment: Yes = 1; No = 0
21	Relationships/engagement	Did teachers engage or participate in the way in which they were expected to?	Direct assignment: Good reported throughout = 1; Some weaker evidence of good relationships = 0.75; Missing/NA/Unclear = 0.5; Weaker evidence of poorer relationships = 0.25; Poor relationships = 0
		Did parents engage in the way in which they were expected to?	Direct assignment: Good reported throughout = 1; Some weaker evidence of good relationships = 0.75; Missing/NA/Unclear = 0.5; Weaker evidence of poorer relationships = 0.25; Poor relationships = 0

		Did school nurses engage in the way in which they were expected to?	Direct assignment: Good reported throughout = 1; Some weaker evidence of good relationships = 0.75; Missing/NA/Unclear = 0.5; Weaker evidence of poorer relationships = 0.25; Poor relationships = 0
		Did other stakeholders engage in the way in which they were expected to?	Direct assignment: Good reported throughout = 1; Some weaker evidence of good relationships = 0.75; Missing/NA/Unclear = 0.5; Weaker evidence of poorer relationships = 0.25; Poor relationships = 0
		Process Outcomes	
22	Child satisfaction	Level of satisfaction (%) or record qualitative statement on child satisfaction with the intervention. Indicators of satisfaction included children reporting that they enjoyed the intervention; whether children would recommend the intervention; whether children found the intervention helpful. Knowledge development not included here	Elements of direct and transformational assignment. Direct assignment: Where there is a qualitative statement indicating positive agreement = 0.66; where a qualitative statement indicating negative agreement = 0.33; no data = 0.5 Transformational assignment: Interventions with 25% or fewer children satisfied = 0; interventions with 50% children satisfied = 0.5; missing data = 0.5; interventions with 75% or more children satisfied
23	Child attrition	Put in level of completion (%) or record qualitative statement on child completion rate	Elements of direct and transformational assignment. Note thresholds are higher than satisfaction as there are fewer missing data. Direct assignment: Where there is a qualitative statement indicating high level of completion = 0.83; where a qualitative statement indicating problematic completion = 0.66; missing data = 0.75 Transformational assignment: Interventions with 66% or fewer children completing the intervention = 0; interventions with 75% of children completing the intervention = 0.5; intervention with 83% or more children completing the intervention = 1. Missing data = 0.5
24	Child dosage level	Did the children receive the intended dosage of the intervention (%) or record qualitative statement?	Elements of direct and transformational assignment. Note thresholds are higher than satisfaction as there are fewer missing data. Direct assignment: Where there is a qualitative statement indicating high level of dosage = 0.83; where a qualitative statement indicating problematic dosage = 0.66; missing data = 0.75 Transformational assignment: Interventions with 66% or fewer children receiving the full dosage = 0;

			interventions with 75% of children receiving the full dosage = 0.5; interventions with 83% or more children receiving the full dosage = 1; missing data = 0.5
25	Child adherence	Did the children adhere to the intervention instructions?	Elements of direct and transformational assignment. Note thresholds are higher than for satisfaction as there are fewer missing data. Direct assignment: Where there is a qualitative statement indicating high level of adherence = 0.83; where a qualitative statement indicating problematic adherence = 0.66; missing data = 0.75 Transformational assignment: Interventions with 66% or fewer children adherent = 0; interventions with 75% of children adherent = 0.5; interventions with 83% or more children adherent = 1; missing data = 0.5
26	Consolidated process variable	Summation of attrition, adherence and dosage scores as a marker of implementation success	Transformational assignment: Implementation not successful = 0; mid-point between successful and unsuccessful implementation = 1.5; full implementation success = 3

Table 23. Detailed coding framework for conditions and outcomes

5.3.3 Search Methods for Identification of Studies

Electronic searches

The Cochrane airways group specialised register was searched using the search strategy included in appendix 10. This strategy was developed by the Cochrane Airways Information Specialist (Liz Stovold). The searches were conducted in April 2015 and updated in April 2016 and August 2017.

Searching other resources

As this review included process evaluation studies for the QCA, the search was expanded to identify process evaluation studies as well as RCTs for the meta-analyses. Thee searches were based on the search criteria included in appendix 10, however they were adjusted to account for the different search syntax/parameters used in additional databases. The search strategies can be found in appendix 11. The databases included:

i. Database of Promoting Health Effectiveness Reviews (DoPHER)

ii. Cochrane Database of Systematic Reviews (CDSR)

iii. Database of Abstracts of Reviews of Effects (DARE)

iv. The Campbell Library

v. National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme website/journals library

vi. HTA Database

Search strategies were also applied to a comprehensive search of the databases below from 1995 to present:

i. Applied Social Sciences Index and Abstracts (ASSIA)

ii. BiblioMap (EPPI-Centre Database of Health Promotion Research)

iii. CDSR

iv. Cochrane Central Register of Controlled Trials (CENTRAL)

v. Health Management Information Consortium (HMIC)

vi. International Bibliography of the Social Sciences (IBSS)

vii. National Health Service Economic Evaluation Database (NHS EED)

viii. PubMed

ix. Sociological Abstracts (SOCABS)

x. Social Policy and Practice (SPP)

xi. Social Services Abstracts

xii. Web of Knowledge

Google Scholar, Social Policy Digest and other sources such as the BTS and Asthma UK were also hand searched.

Integral process evaluations (sibling studies) were identified through backwards and forwards citation searches initially.

5.3.4 Data Collection and Analysis

Selection of studies

The inclusion criteria were applied to titles, abstracts, and full reports, which were entered into EPPI-Reviewer [183]. Studies that met the inclusion criteria based on title and abstract

screening, or studies that did not provide enough information in the abstract to decide, were included, and the inclusion criteria were applied to the full-text reports. The inclusion criteria are outlined below:

(i) Population (children aged 5-18 years)

(ii) Disease status (physician diagnosis of asthma)

(iii) Intervention (school-based, with a focus on self-management)

(iv) Comparison (lower intensity or usual care)

(v) Study design (RCT)

(vi) Date (published after 1995)

(vii) Language (English)

For process evaluation studies, additional screening criteria were applied. This included the use of recognised tools to collect the data, and excluded studies that did not include the core components that would be expected within a process evaluation (as identified by the MRC and described above).

During the pilot screening process, two review authors independently screened a random selection of studies on title and abstract, and participated in moderation exercises to discuss the screening results, and ensure consistency in applying the review exclusion criteria. Disagreements were discussed and resolved accordingly. An agreement rate of 90% or above was required, and was achieved in three consecutive samples, before independent screening on the rest of the studies began.

5.3.5 Data Extraction and Management

Data management

The studies that were identified in the searches were uploaded to EPPI-Reviewer 4 for duplicate stripping and screening [183]. Using EPPI-Reviewer 4, the outcome of the screening process was recorded, with reasons for exclusion. The included studies were subsequently exported into StataCorp 2013 and RevMan 5.3, for analysis.

Outcome measures – data extraction

Two review authors independently extracted the study characteristics and numerical outcome data from studies meeting the eligibility criteria of the review. No disagreements were encountered that needed to be resolved by senior members of the review team. Where missing data was found, the study authors were contacted for further information.

Process Evaluation measures – Data selection

The aim of the process evaluation component of this review was to identify the combinations of components and processes within interventions that are associated with successful intervention implementation.

Two review authors independently extracted conditions of interest from the process evaluation studies that met the eligibility criteria of this review. The first step was to build a data table of information supporting several conditions (over 90) for each study. These data represented both quantitative indicators, which represented the degree to which a condition was present (e.g. the number of students from an ethnic minority in an intervention); binary indicators, which represented whether a condition was present or not (e.g. asthma curriculum contained information on lung physiology); or qualitative statements (e.g. published quotes of student satisfaction with the intervention). An example from this review includes whether an intervention took place within a high school. Interventions that took place exclusively within high schools were assigned a value of 1 (fully within the set); those that took place exclusively within primary/elementary schools were assigned a value of 0. Where values were directly assigned in this way, no further adjustment was required. In other cases, a combination of direct and transformational assignment was required. In direct assignment, values were directly assigned, which are typically based on categorical or binary source indicators. In transformational assignment, rules are developed for how continuous values are coded between 0 and 1. A score of 1 indicates full set-membership, and 0 indicates that the study is out of the set. Membership scores of 0.5 indicate that the study is neither in nor out of a set, and this value was used for some of the missing data that was seen in this review.

More data was extracted than could be supported by any of the QCA models (known as limited diversity). Many of the conditions that were extracted were binary indicators of concepts relating

to the same condition; therefore cluster analyses were applied, to create natural groupings and reduce the number of conditions in some of the models [175]. The original and reduced data are displayed for these conditions in table 24.

Curriculum – Original Conditions		Curriculum – Reduced Conditions	
i.	Lung physiology	i.	Symptom monitoring and alliances
ii.	Asthma acceptance	ii.	Lung physiology and general health
iii.	Symptom monitoring and treatment	iii.	Symptom monitoring and trigger avoidance
iv.	Trigger avoidance	iv.	Other various foci
v.	General health	v.	Unknown
vi.	Forming alliances		
vii.	Smoking		
viii.	Tailored/personalised		
ix.	School performance		
x.	Emergencies		
xi.	Unknown content		
Pedagogical Delivery Style – Original Conditions		**Pedagogical Delivery Style – Reduced Conditions**	
i.	Problem solving	i.	Interactive focused style
ii.	Self-direct	ii.	Diverse style
iii.	Peer delivery	iii.	Unknown style
iv.	Interactive		
v.	Didactic		
vi.	No information/other focus		
Intervention Emphasis – Original Conditions		**Intervention Emphasis – Reduced Conditions**	
i.	Emphasis on social benefit	i.	Emphasis on tailoring/personalisation
ii.	Emphasis on wellbeing	ii.	Emphasis on personal responsibility
iii.	Emphasis on having fun	iii.	Diffuse emphasis/other
iv.	Emphasis on personal responsibility		
v.	Emphasis on children's knowledge		
vi.	Emphasis on collaboration		
vii.	Emphasis on tailoring/personalisation		
viii.	Emphasis unclear		

Table 24. Original and reduced conditions for curriculum content, delivery style and programme emphasis

Although the cluster analysis reduced the number of conditions, the focus of the review was on studies that were either high or medium intensity, as this is consistent with indicators such as attrition and dosage. Therefore, six reports of interventions that involved one or two face-to-face sessions [184-189] were excluded from the analysis.

5.3.6 Assessment of risk of bias in included studies

The sources of bias below were assessed in terms of how they were believed to affect the results of an individual outcome evaluation study:

- **Sequence generation:** studies that used a computer-generated allocation procedure, a random number table, or other recognised low-risk means were deemed to be at low risk of bias (per the tool of the Cochrane Collaboration for assessing risk of bias). Studies that

used procedures such as clinic visit date or date of birth, where the order of treatment group assignment was predictable or open to external influence, were deemed to be at high risk of bias. Where the method of randomisation could not be identified, the study was classified as having an unclear risk of bias. Due to the potential impact of socioeconomic imbalance between cluster sites within the same study, consideration was also given to whether stratification on socioeconomic variables was undertaken.

- **Allocation concealment:** Studies for which measures were taken to prevent disclosure of treatment group assignment, such as off-site allocation or allocation by a third part not involved in the study, were deemed to be at low risk of bias. For cluster-randomised studies, an additional consideration was timing of recruitment into the study in relation to assignment.
- **Blinding (performance bias and detection bias):** Studies for which measures were taken to ensure that personnel collecting data were unaware of participants' treatment group assignment were low risk of bias. However, given the nature of the intervention and the difficulty involved in blinding recipients, a degree of performance bias may have impacted some outcomes, and particularly patient reported outcomes, which was unavoidable.
- **Handling of missing data and attrition:** Studies for which data sets were complete, or for which reasons for missing data were not related to treatment, were low risk of bias. When attrition rates were high, imbalanced or unexplained, and only an available study set is presented, the study was deemed to be at high risk of bias. Studies for which the attrition rate was not reported separately for treatment and control groups, and for which the reasons for withdrawal could not be ascertained were also deemed high risk of bias.
- **Selective reporting:** Assessments of selective reporting were restricted to examination of the availability of data related to outcomes included in the summary of findings (SoF) table in table 25.
- **Other bias:** Baseline imbalances were examined in the characteristic of participants for potential bias. The evidence of contamination between intervention and control groups

was also considered. Sensitivity analysis was restricted to the primary outcomes of the review. The overall judgements for each study were derived at the outcome level.

Outcomes	Anticipated Absolute Effects* (95% CI)		Relative Effect (95% CI)	Participants (Studies)	GRADE	Comments
	Risk with Usual Care	Risk with Intervention				
Hospitalisations (follow-up: 1 week to 12 months)	Mean exacerbations leading to hospitalisation was 0.26 episodes (per 12 months)	MD 0.16 episodes (per 12 months) lower (0.294 lower to 0.034 lower)	-	1873 (6)	Moderate	Meta-analysis based on SMD including data transformed from IR; transformation to MD undertaken based on data from Horner 2015 [190] using baseline hospitalisation level in control group
ED visits (follow-up: 1 week to 12 months)	Moderate 75 per 1,000 High 281 per 1,000	54 per 1,000 (41 to 69) 215 per 1,000 (172 to 264)	OR 0.70 (0.53 to 0.92)	3883 (13)	Low	Assumed risk based on rates over 12 months. Less than 10% based on 3 studies [191-193]; more than 10% based on 2 studies [194, 195]
Unplanned visit to hospital or GP (follow-up: 1 week to 12 months)	Low Moderate 318 per 1,000	 210 per 1,000 (177 to 244) 257 per 1,000 (219 to 296)	OR 0.74 (0.60 to 0.90)	3283 (5)	Moderate	Unplanned visits over 6-9 months based on 2 studies [195, 196]; Unplanned visits over 12 months based on 2 studies [192, 194]
Absence from school (follow-up: 1 week to 15 months)	Mean absence = 4.3 school days missed annually	MD 0.399 school days missed annually lower (1.254 lower to 0.456 higher)	-	4609 (10)	Low	Meta-analysis based on SMD including data transformed from OR; transformation to MD undertaken based on data from 1 study [197]
Experience of day time symptoms (follow-up: 2 months to 12 months)	Mean experience of symptoms was 3 days experienced in past 2 weeks	MD 0.377 days experienced in past 2 weeks lower (0.828 lower to 0.05 higher)	-	1065 (5)	Moderate	The CI for this pooled estimate crossed the line of no effect by a small margin. Original meta-analysis based on SMDs, including transformations from ORs. SMD to MD based on 1 study [95]

Use of reliever therapies (follow-up: 1 week to 15 months)	Study population 228 per 1,000	133 Per 1,000 (42 to 349)	OR 0.52 (0.15 to 1.81)	437 (2)	Very Low	-
HRQoL (follow-up: 1 week to 12 months)	Mean HRQoL was 4.96 PAQLQ points	MD 0.36 PAQLQ points higher (0.06 higher to 0.64 higher)	-	2587 (7)	Moderate	Two studies provided information on change in QoL. Both showed positive intervention effects, but with high heterogeneity. Risk with usual care based on follow-up scores

*The risk in the intervention group (and its 95% CI) 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; **HRQoL:** Health-Related Quality of Life; **RR:** Risk Ratio; **OR:** Odds Ratio; **QoL:** Quality of Life; **SMD:** Standardised Mean Difference; **PAQLQ:** Paediatric Asthma Quality of Life Questionnaire

GRADE: **High:** very confident that the true effect lies close to that of the estimate of the effect; **moderate:** moderately confident in the effect estimate. The true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different; **low:** confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect; **very low:** very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect

Table 25. Summary of Findings for the Main Comparison

The quality of the process evaluation studies were assessed using two tools. The first tool was developed at the EPPI-Centre [198] to assess the methodological rigour of 'views' studies that aimed to collect information on people's experiences from trials. This tool considers seven criteria:

i. Whether the study includes an explicit theoretical framework and/or literature review;
ii. Clearly state aims and objectives;
iii. A clear description of context;
iv. A clear description of the sample and how it was recruited;
v. A clear description of methods used to collect and analyse data;
vi. Attempts made to establish the reliability or validity of data analysis;
vii. Inclusion of sufficient original data to mediate between evidence and interpretation

The second tool, which was developed by the EPPI-Centre to assess the quality of process evaluation data [199], assesses:

i. Methods of data collection;
ii. A description of process evaluation participants;
iii. Timing of the process evaluation with respect to the intervention;
iv. Process evaluation data collection methods;
v. Process evaluation data analysis methods;
vi. Whether findings were supported by the data;
vii. Breadth and depth of findings;
viii. The extent to which the process evaluation gave privilege to the views of participants;
ix. Reliability of findings;
x. Usefulness of process evaluation

As some of the domains from these tools overlap, elements from both tools were combined to assess the quality of process measures.

5.3.7 Assessment of bias in conducting the review

The review was conducted in accordance with the published protocol [200].

5.3.8 Measures of treatment effect

Continuous Data

As recommended in the Cochrane Handbook for Systematic Reviews of Interventions [201], mean differences (MDs) were intended to be calculated when continuous data were measured by the same scale or unit. However, this did not occur for most of the outcomes in this review. Therefore, when similar outcomes were measured by different scales or units, standardised mean differences (SMDs) were used.

Dichotomous Data

For dichotomous (binary) data, odds rations (ORs) were calculated, and when appropriate, combined results from different trials

Ordinal Data

As set out in the Cochrane Handbook for Systematic Reviews of Interventions [201], ordinal outcomes (e.g. quality of life scales) were to be analysed as continuous variables. When appropriate thresholds were identified, these were analysed as dichotomous variables.

Count Data

Rate ratios were calculated for all count data that were encountered that represented the ratio of events experienced between two groups, such as hospitalisations or absences from school.

5.3.9 Unit of analysis issues

Cluster-Randomised Studies

Cluster-randomised controlled studies were included in which schools or classes within schools, rather than individual with asthma, were the unit of allocation. Variation in response to treatment between clusters may also be influenced by cluster membership, meaning that cluster members' data can no longer be considered independent of one another. Therefore, data were extracted when study authors had adjusted for a clustered design in the analysis. Where no Intracluster Correlation

Coefficient (ICC) was provided, an ICC of 0.05 was chosen, based on the ICC estimate used in one of the included papers to calculate the sample size [187]. Effect estimates were adjusted using the methods described in the Cochrane Handbook [201].

Choice of Measurement Point

For trials that reported outcomes at multiple time points, such as post-test with longer follow-up, all data extracted and combined in meta-analyses were the follow-up point most consistently reported among trials.

5.3.10 Dealing with missing data

When data were missing from studies, the authors were contacted directly to obtain the missing information. Table 26 highlights the details of the studies which had missing data and were therefore excluded from the meta-analysis.

Study Included as Outcome	Reason Data not Included in Meta-Analysis
Bruzzese 2004	Feasibility study using RCT design with no quantitative data presented
Bruzzese 2010	Abstract only located and outcomes not presented in an extractable format
Clark 2004	Published effect sizes that were extractable but of a different effect size from other studies
Clark 2010	No outcome measured in the study matched the review protocol
McCann 2006	Outcomes were not presented in an extractable format (disaggregated data for asthmatic children unavailable)
Monforte 2012	Abstract only located and outcomes not presented in an extractable format
Monsnaim 2011	No outcome measured in the study matched the review protocol
Praena-Crespo 2010	Abstract only located and outcomes not presented in an extractable format
Pulcini 2007	No outcome measured in the study matched the review protocol
Srof 2012	Outcomes were not presented in an extractable format (QoL data were not presented in full)

Table 26. Outcome evaluation studies not included in the analysis

5.3.11 Assessment of heterogeneity

Statistical heterogeneity was assessed by using the I^2 measure [202]. Pre-specified sensitivity and subgroup analyses were conducted to explore possible sources of variation.

The relatively low number of studies in the meta-analysis models (the largest model included 13 studies) meant that random-effects multivariate meta-regression models could not be constructed, without comprising the underlying assumptions of the models.

5.3.12 Assessment of reporting biases

The number of studies in which the analysis of data related to the primary outcomes of this review could not be identified was recorded. The distribution of effect sizes for each outcome study was plotted against the study standard errors (SE) as a funnel plot for the primary outcomes, and the publication bias assessment was based on a visual inspection, if 10 or more studies contributed to the outcome. Formal tests for small-study publication bias were also conducted, using Egger's test [203].

5.3.13 Data Synthesis

Outline of approach to synthesis

The synthesis in this review takes a multifaceted approach to understanding (i) the components that are required to successfully deliver a school-based asthma intervention, and (ii) the impact that school-based interventions can have on children's outcomes.

In the analysis one, QCA was conducted to highlight which combinations of intervention characteristics (known as conditions) are associated with successful implementation. The QCA aimed to generate hypotheses about the importance of different intervention components and processes that were later tested in the meta-analyses. The conditions that were identified not only helped to identify which conditions are important for successfully implementing an intervention, but also helped to structure the meta-analysis and identify their potential impact on the overall effectiveness of interventions on children's outcomes. The possibility that hypotheses were generated and tested on the same dataset was avoided due to little overlap between studies being included in the QCA and studies being included in the meta-analyses. Studies included in the QCA included a wide range of study designs.

In part two of the analyses, the effectiveness of school-based asthma self-management interventions in improving children's outcomes were examined by conducting meta-analyses of the primary and secondary outcomes. Only those with an RCT design were included in the meta-analysis of outcome evaluation studies. Additional subgroup analyses, based on the results of the QCA, were also conducted.

In part three of the analyses, the link between implementation and effectiveness was examined, through estimating whether interventions defined as 'successful' in terms of their implementation were also those with higher effect sizes. These analyses took place on a subgroup of studies adopting varied study designs.

Process-level measurements using QCA

QCA takes a study-based approach (accounting for several study characteristics simultaneously), so that the focus is on different combinations of conditions [175]. Notably, this approach is relatively new to systematic reviewing. The QCA approach used in this review aimed to generate theories about components that were 'sufficient' to trigger successful implementation 'Sufficient' relationships indicate that an outcome is triggered in the presence of a condition or condition set; however, other pathways to achieving the outcome may also exist'.

The QCA analyses presented in this review are fuzzy-set QCA (fsQCA), which reflects both the concepts being tested, and the data that is being used. In fsQCA, the main interest is establishing set membership scores, which indicates the extent to which studies below to a set, with values falling between 0 and 1 (as described above). A set membership score for each study was calculated based on the study conditions from the data table, and these were analysed against the outcome membership scores.

During the data analysis, the recommendations given by Ragin [204] and Thomas [175] were followed. First, a data table for each study was developed, which displayed its assigned values. Following this, a truth table was developed, which showed the data on each combination of conditions, instead of just showing the data for each study. Combinations could be supported by multiple studies, or a single study. Possible combinations could also not be supported by any data (referred to as a logical remainder). A consistency score was also included in the truth table, which showed the degree that membership in the combination of conditions is a subset of the degree of membership in the outcome set. A fairly high value of 0.875 was applied before a combination could be considered to trigger an outcome. The quality of the truth table was then checked and contradictory combinations (where the same combination supports the outcome and its negation) were resolved. Boolean minimisation was then included, which identifies the simplest explanation

of the results. Where logical remainders were found, these were incorporated into further models to simplify the solution and maintain its theoretical consistency.

Quantitative Data

Data were combined which explored the effect of an intervention compared to either usual care or an intervention that did not include asthma education. Two studies compared the intervention to a placebo intervention, instead of usual care, therefore no further disaggregation of this comparison was made.

The data was combined in Review Manager 5.1 [205], however some analyses and data transformations were also conducted in Stata (where cluster-randomised trials were encountered the standard errors were converted using EPPI-Reviewer; [183]). Several variations were seen, and Chinn's formulae [206] was used to convert effect sizes and standard errors between SMDs and ORs.

Occasionally, some data could not be included in the meta-analyses due to methodological difficulties in combining the data. This included data based on the median. Some other changes and forms of imputation for missing data included:

i. Basing the effect size for quality of life for Al-Sheyab 2012 [207] on the p-value because of uncertainty regarding the effect size derived from the point estimates and precision provided;

ii. Basing the effect sizes for Cicutto 2013 [194] on approximations of the number of participants in control and treatment groups;

iii. Estimating the number in the treatment and control arms for Clark 2005 [208], assuming an equal distribution of the overall sample size. For this study, an OR of 0.996 was also inputted for a value reported as 1.00 for emergency department (ED) visits, in order to be able to combine the information in models.

5.3.14 Rating the quality of the evidence

The quality of the evidence was rated using methods developed by the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) Working Group

(http://www.gradeworkinggroup.org/publications/JCE_series.htm). The possible impact of each of the following were factors on each of the outcomes of interest were explored:

- Risk of bias
- Imprecision
- Inconsistency
- Indirectness
- Publication bias

The GRADE ratings were entered in a table alongside absolute and relative effects in the summary of findings table in table 25 for the following outcomes:

- Asthma symptoms or exacerbations leading to admission to hospital
- Asthma symptoms or exacerbations leading to ED visits
- Unplanned visit to hospital or GP due to asthma symptoms
- School absence
- Experience of daytime symptoms
- Use of reliever therapies
- Health-related quality of life (HRQoL)

5.3.15 Subgroup analysis and heterogeneity

An I^2 statistic was used to calculate heterogeneity across subgroups. The aim was to develop a multi-variate meta-regression model, based on the results for the different outcomes. However, the low number of studies did not allow for this. Instead, subgroup analyses were conducted to investigate heterogeneity on the basis of the following characteristics:

- Setting
- Age
- Socioeconomic level
- Delivery of intervention
- Other factors (e.g. theory-driven)

Some indicators, such as socioeconomic status, were measured differently, therefore the groupings were based on income, social class, or other indicators of social position, such as being

in receipt of means tested benefits, were used. None of the interventions were based on asthma severity, therefore sensitivity analyses were not conducted on this basis.

The process evaluation analysis was conducted before the RCTs to remain blinded to the possible impact of specific measures.

5.3.16 Sensitivity Analyses

Sensitivity analyses were based on the following:

- Risk of bias assessment: All studies were included in the primary analysis and then restricted included studies to those that were not classified as having a high risk of bias for any single domain
- Fixed-effect modelling
- Exclusion of cluster study data from outcomes

An equivalent was not applied for the QCA modelling, however checks for robustness were conducted, including whether solutions predicted the negation of the outcome.

5.4 Results

5.4.1 Description of Studies

Thirty-three process evaluation studies, and thirty-three separate outcome evaluation studies, met the inclusion criteria and were included in the review. The characteristics of all included studies are reported in the characteristics of included studies tables in table 27 and table 28.

An additional table summarises how the process evaluations met the inclusion criteria (table 29).

Methods				Participants					Intervention				
Author	**Design**	**Setting**	**Sample Size**	**Age**	**Ethnicity**	**SES**	**Gender**	**Asthma Status**	**Description**	**Control**	**Intensity**	**Instructor**	**Theory**	**Outcomes**
Al-Sheyab 2012	Cluster parallel RCT	Jordan High Schools	261	Years 8-10	None	None	43.3% female	70.5% diagnosis	Triple-A	Usual Care	3 Lessons	Peers	Self-Efficacy	HRQoL, Withdrawal
Atherly 2009	Cluster parallel RCT	Junior High and High Schools	458	Mean age 13.9	None	None	48% female	Asthma only	Power Breathing	Not Reported	3 Lessons	Teachers and School Nurses	None	Hospital admissions, Day and night-time symptoms, ED visits
Bartholomew 2006	Cluster parallel RCT	Texas Elementary Schools	503	Mean age 7.7	45% African American	Most <$20,000 annual income	52.1% Male	None	Asthma education	Usual Care	Not Reported	Computer Programme	Social Cognitive Theory	Withdrawal
Bruzzese 2004	RCT	High School	45	9th and 10th grade	None	None	None	Asthma only	OAS	Usual Care	3 Lessons	Health Educator	Self-Regulation Theory	None
Bruzzese 2008	Parallel RCT	NYC Middle School	24	Mean age 12.8	41% Hispanic	71% Full-time work	54% male	None	OAS, ASMA, Caregiver Education	Usual care	Six weekly sessions	Psychologist	Social cognitive theory	Symptoms, withdrawal
Bruzzese 2010	Parallel RCT	NYC Public School	288	14-16 Years	45.5% Hispanic	75% Free School Meals	None	Asthma only	ASMA. Academic Detailing	Usual care	6 Lessons	Not Reported	Social Cognitive Theory	Withdrawal
Bruzzese 2011	Parallel RCT	NYC High Schools	345	Mean age 15.10	45.5% Hispanic	None	70.4% female	Asthma only	ASMA	Usual care	Three sessions over 8 weeks	Health Educators	Social Cognitive Theory	Hospital admissions, hospital visits, school absence, restricted activity, unplanned GP or hospital visit, symptoms, corticosteroid dosage, withdrawal
Cicutto 2005	Cluster parallel RCT	Elementary schools in Toronto	256	Mean age 8.6	None	None	59.6% male in control		Roaring Adventures of Puff	Usual care	Six weekly sessions	Asthma educator	Social Cognitive Theory; Self-Regulation Theory	Hospital admissions, hospital visits, school absence, restricted activity

Cicutto 2013	Cluster RCT	Elementary schools	1316	8 years	None	None	57.4% male	Asthma only	Roaring Adventures of Puff	Usual care	Six weekly sessions	Public health nurse	Social Cognitive Theory	Hospital visits, school absence, restricted activity, unplanned GP or hospital visit, HRQoL, withdrawal
Clark 2004	Cluster parallel RCT	High schools in Detroit	835	Grade 2 to 5	98% African-American	45% <$15k	None	Asthma only	Open Airways for Schools	Usual care	Six weekly sessions	None	None	School absence, symptoms
Clark 2005	Cluster parallel RCT	Elementary schools in Beijing	639	7-11 years	None	None	None	Asthma only	Open Airways for School	Usual care	Five weekly sessions	Teachers	Social Cognitive Theory	Hospital admission, hospital visits
Clark 2010	Cluster parallel RCT	Middle schools in Detroit	1292	Mean age 11.6	93% African-American	44%-50% <15k	48% female	Asthma only	Open Airways for School	Usual care	Six weekly sessions	Graduate students and community leaders	None	Symptoms
Gerald 2006	Parallel group	Elementary schools	736	Grade 1-4	97% Black	None	5% male control	None	Open Airways for School	Usual care	Six weekly sessions	Teachers and study personnel	None	Hospital admissions, hospital visit, school absence
Gerald 2009	Parallel group	None	290	Mean age 11.0	91% Black	None	57% male	Asthma only	Asthma education (unspecified)	Usual care	Single session	Study personnel	None	School absence, lung function, use of reliever therapy, withdrawal

Henry 2004	Cluster parallel RCT	Secondary schools Australia	4475	13-14 years	Majority Caucasian	None	52% male	None	Asthma education (unspecified)	Usual care	Three lessons	Teacher	None	HRQoL
Horner 2008	Cluster parallel RCT	Elementary schools	183	Mean age 8.78	47% Mexican	None	108 males	None	Asthma self-management plan	Health education	16 sessions	Health educators	Theoretical Model of Asthma	Hospital admissions, withdrawal
Horner 2015	Cluster parallel RCT	Elementary schools in Texas	292	Mean age 8.8	60.8% Hispanic	30% low SES	60% male	Asthma only	Asthma Plan for Kids	Health education	16 sessions over 5 weeks	Health educators	Theoretical Model of Asthma	Hospital admissions, hospital visits, withdrawal
Howell 2005	Cluster parallel RCT	Syracuse Elementary Schools	25	8-11 Years	75% African-American	None	63% Male	Asthma only	Quest for the Code	Usual care	4 Lessons	Computer Programme	Learning Theory	None
Kintner 2009	Cluster parallel RCT	Schools in Michigan	66	Mean age 10.5	32% African-American	None	52% male	Asthma only	Staying Healthy-Asthma Responsible and Prepared	Usual care	10 sessions	None	Lifespan Development	HRQoL, withdrawal
Levy 2006	Cluster parallel RCT	Elementary schools in Memphis	243	6-10 years	98% African-American	83% TennCare	58% male	None	Open Airways for School	Usual care	Weekly sessions	School nurse	None	Hospital admissions, hospital visits, withdrawal
McCann 2006	Cluster parallel RCT	Primary schools in England	219	7-9 years	None	20% low SES	122 males	Asthma and non-asthma	Asthma education (unspecified)	Health education	One session	School nurse	None	None
McGhan 2003	Cluster parallel RCT	Elementary schools in Canada	162	5-13 years	77.8% White	None	59.2% male	Asthma only	Roaring Adventures of Puff	Usual care	Six weekly sessions	Nursing and pharmacy students	Social Cognitive Theory	Hospital visits, school absence, unplanned GP or hospital visit, symptoms, withdrawal
McGhan 2010	Cluster parallel RCT	Elementary schools in Canada	162	7-12 years	78% Caucasian	None	60% male	Asthma only	Roaring Adventures of Puff	Usual care	Six weekly sessions	Nursing and pharmacy students	Social Cognitive Theory	Hospital visits, school absence, unplanned GP or hospital visit, symptoms, withdrawal

Monforte 2012	Cluster parallel RCT	Elementary schools	90	Grade 3 to 6	None	None	None	Asthma only	Open Airways for Schools	None	None	None	None	HRQoL
Mosnaim 2011	Cluster parallel RCT	Elementary schools in Chicago	552	5-10 years	Majority African-American	None	43% female	None	Individual asthma education	Usual care	Four daily sessions	Asthma educators	None	None
Patterson 2005	Cluster parallel RCT	Primary schools in Belfast	176	Mean age 9.0	None	27% low SES	50% male	None	Asthma education (unspecified)	Usual care	8-weekly sessions	School nurse	PRECEDE model	Restricted activity, lung function, HRQoL, withdrawal
Persaud 1996	Parallel group RCT	Schools in Texas	36	Mean age 10.2	69% African-American	69% low SES	64% male	Asthma only	Asthma education (unspecified)	Usual care	3 lessons	School nurse	None	Hospital visits, school absences
Praena-Crespo 2010	Cluster parallel RCT	High schools	3827	13-14 years	None	None	Mixed	Asthma and non-asthmatic	Asthma education (unspecified)	None	3 lessons	Teacher	None	None
Pulcini 2007	Cluster parallel RCT	Middle schools	40	Grade 6-8	None	None	None	None	Peak flow education	Usual care	2 weeks' daily	School nurse	None	None
Shah 2001	Cluster parallel RCT	High schools in Tamworth	272	Years 7-10	None	None	Majority female	69%-80% asthmatic	Asthma education (unspecified)	Usual care	None	Peers	None	Symptoms, lung function, HRQoL, withdrawal
Splett 2006	Cluster parallel RCT	K-8 schools in Minneapolis	1561	None	66% African-American	73% low SES	58% male	None	Asthma education (unspecified)	Usual care	None	School nurse	None	School absences, unplanned GP or hospital visit
Srof 2012	Parallel group RCT	High schools	39	Mean age 15.7	None	None	11 females	None	Asthma diary and coping skills	Usual care	Daily sessions for 5 weeks	PI	Health Promotion Model	None
Velsor-Friedrich	Cluster parallel RCT	Elementary schools	73	Mean age 10	100% African-American	None	50% male	Asthma only	Open Airways for schools	Usual care	6 group sessions	PI and nurse	Self-Care Deficit Theory	Hospital visits, symptoms, lung function

Table 27. Characteristics of included studies: Outcome Evaluation

	Methods			Intervention Participants					Intervention				Outcomes	Notes		
Author	**Design**	**Unit of Allocation**	**Process Evaluation Methods**	**Country**	**Age**	**Characteristics**	**Asthma Status**	**Recipients**	**School**	**Description**	**Control**	**Theoretical Framework**	**Core Processes Evaluated**	**Process Evaluation Category**	**Breadth or Depth**	**Child's Voice**
Al-Sheyab (2012)	Case study	n/a	Unstructured analysis	Jordan	7-11 years	None	None	Children	High	Triple A	n/a	None, but based on development stages and peer impact	None	Standalone	Neither broad or deep	Featured, but not sufficient
Berg (2004)	Quasi; post-test	n/a	Descriptive/ bivariate (surveys), thematic or grounded theory	USA	15-18 years	46.2% African-American	Asthma only	Children	High	Power Breathing, individual coaching	n/a	Social Learning Theory	Attrition, adherence	Integrated	Neither broad or deep	Sufficient
Bignall (2015)	RCT Parallel Group	Child	Descriptive/ bivariate (quantitative) and descriptive (qualitative)	USA	12-17 years	100% African-American	Asthma only	Children	High	Single workshop for children	Non-equivalent	None	Attrition, dosage, adherence	Named section	Neither broad or deep	Featured, but not sufficient
Brasler (2006)	Case study	n/a	Univariate analysis	USA	11-13 years	None	Asthma only	Children	Junior/ Middle	Power Breathing	n/a	None	Attrition, dosage, adherence	Named section	Breadth and depth	Featured, but not sufficient
Bruzzese (2004)	RCT Parallel Group	Child	Descriptive/ bivariate (quantitative)	USA	14-16 years	None	Asthma only	Children	High	Open Airways for School (OAS), Academic Detailing	Usual care	Self-Regulation Theory	Attrition, adherence	Standalone	Neither broad or deep	Sufficient
Bruzzese (2008)	RCT Parallel Group	Child	Descriptive/ bivariate	USA	Mean: 12.9 years	41% Hispanic	Asthma only	Children and parents	Junior/ Middle	OAS, ASMA, Caregiver education	Usual care	Social Cognitive Theory	Attrition, dosage, adherence	Named section	Neither broad or deep	Featured, but not sufficient
Bruzzese (2010)	RCT Parallel Group	Child	Descriptive/ bivariate and multivariate	USA	14-16 years	45.51% Hispanic; 75% free school meals (FSM)	Asthma only	Children	High	ASMA, Academic Detailing	Usual care	Social Cognitive Theory	Attrition, dosage, adherence	Integrated	Neither broad or deep	Featured, but not sufficient

Carpenter (2016)	Quasi; pre-post	n/a	Descriptive/ bivariate	USA	7-17 years	72% Non-Hispanic White	Asthma only	Children and nurses	All	Multiple session workshops for children	n/a	Thematic Grounded Theory	Adherence	Named section	Neither broad or deep	Sufficient
Cicutto (2013)	Cluster RCT	School	Descriptive/ bivariate	Canada	8 years	25% deprived	Asthma only	Children with asthma and the broader community of schools	Primary	Roaring Adventures of Puff (RAP)	Usual care	Social Cognitive Theory	Attrition	Standalone and Integrated (two papers)	Breadth, not depth	Not featured
Crane (2014)	Quasi; pre-post	School	Quantitative	USA	8-12 years	None	Asthma only	Children	Primary	Modified OAS	OAS (standard)	Piaget's educational theory	Attrition, dosage	Standalone	Depth, not breadth	Featured, but not sufficient
Dore-Stites (2007)	Quasi; pre-post	n/a	Descriptive/ bivariate (hypothesis testing)	USA	5-10 years	39% African-American; 34.6% low income family	Asthma only	Children and parents	Primary	OAS, Quest for the Code, Materials for parents	n/a	None	Attrition	Integrated	Neither broad or deep	Sufficient coverage
Engelke (2013)	Quasi; pre-post	n/a	Bivariate	USA	Grades 1-12	40.6% Caucasian; 63.6% Medicaid	Asthma only	Children, teachers, parents, nurses	All	Case management, additional nurse meetings, multiple session workshop for children and staff	n/a	None	None	Named section	Depth, not breadth	Not featured
Gerald (2006)	Cluster RCT	School	Descriptive/ bivariate (hypothesis testing)	USA	6-10 years	97% African-American	Asthma only	Children and teachers	Primary	OAS, integrated into curriculum, multiple session workshop for children and staff	Usual care	None	Attrition, dosage, adherence	Named section	Neither broad or deep	Not featured

Henry (2004)	Cluster RCT	School	Descriptive/ bivariate	Australia	13-14 years	Predominantly Caucasian	Asthma and non-asthma	Children and teachers	High	Multiple session workshop for children	Usual care	None	Adherence	Integrated	Depth, not breadth	Featured, but not sufficient
Horner (2015)	Cluster RCT	School	Multivariate (latent class analysis)	USA	Grades 2-5	21.2% African-American; 30.7% lower SES	Asthma only	Children	Primary	Multiple session workshop for children (asthma plan)	Equivalent	Theoretical Model of Asthma Self-management	Attrition, adherence	Integrated	Neither broad or deep	Featured, but not sufficient
Howell (2005)	Cluster RCT	School	Descriptive/ bivariate	USA	8-11 years	75% African-American	Asthma only	Children and parents	Primary	Quest for the Code	Usual care	Learning Theory Principles and Behaviour modification	Attrition, dosage, adherence	Named section	Neither broad or deep	Featured, nut not sufficient
Jackson (2006)	Quasi; pre-post	n/a	Descriptive/ bivariate	USA	8-9 years	None	Asthma and non-asthma	Children	Primary	Single workshop for children	n/a	None	Attrition, dosage, adherence	Integrated	Breadth, not depth	Sufficient
Joseph (2010)	Parallel Group RCT	Child	Multivariate (logistic regression)	USA	Mean: 15.3 years	52% eligible for FSM	Asthma only	Children	High	Puff City, multiple session workshop for children	Equivalent	None	Attrition, dosage, adherence	Standalone and Integrated (two papers)	Breadth and depth	Featured, but not sufficient
Joseph (2013)	Parallel Group RCT	Child	Multivariate (logistic regression)	USA	Mean: 15.9 years	98% African-American; 73% Medicaid	Asthma only	Children	High	Puff City	Equivalent	Behaviour Theory, Health Belief Model, Attribution Theory, Motivational Interviewing	Attrition, dosage, adherence	Standalone and Integrated (two papers)	Breadth and depth	Featured, but not sufficient
Kintner (2012)	Quasi, pre-post	n/a	Descriptive/ bivariate	USA	6-7th Grade	53.6% African-American; 35.7% lower SES	Asthma only	Students, members of social network	High	SHARP, community coalition component	n/a	Asthma model and lifespan development	Dosage, adherence	Standalone	Breadth and depth	Sufficient

Kouba (2012)	Quasi, pre-post	n/a	Descriptive/ bivariate	USA	9-12th Grade	92% African-American	Asthma only	Children	High	Quest for the Code, FAN, nurse meetings, single workshop for staff, multiple workshops for children	n/a	Orem's Self-Care Deficient Theory	Attrition, dosage	Integrated	Depth, not breadth	Not featured
Langenfeld (2010)	Quasi, pre-post	n/a	Bivariate, thematic/ grounded theory	USA	5-10 years	63% African-American; majority eligible for FSM	Asthma only	Children and teachers	Primary	OAS, case management, standalone respiratory therapy, multiple session workshops for children	n/a	None	Dosage	Standalone	Depth, not breadth	Not featured
Lee (2011)	Quasi, pre-post	n/a	Descriptive/ bivariate, narrative data analysis,	USA	8-11 years	None	Asthma only	Children	Primary	OAS	n/a	Thematic/ grounded theory	None	Integrated	Neither broad or deep	Featured, but not sufficient
Levy (2006)	Cluster RCT	School	Descriptive/ bivariate (hypothesis testing included)	USA	6-10 years	Over 97% African-American; over 80% Medicaid	Asthma only	Children and teachers	Primary	OAS, case management, teacher education	Usual care	None	Attrition	Integrated	Breadth, not depth	Not featured
Magzamen (2008)	Quasi, pre-post	n/a	Descriptive/ bivariate	USA	11-16 years	None	Asthma only	Children and teachers	Junior/ Middle and High	Kickin' Asthma	n/a	None	Attrition, dosage, adherence	Standalone and Named Section (two papers)	Depth, not breadth	Not featured
Mickel (2016)	Quasi, pre-post	n/a	Descriptive/ bivariate, descriptive qualitative analysis	USA	Mean: 9.3 years	63.6% African-American	Asthma only	Children	Primary	Iggy, single workshop for children	n/a	None	Attrition, dosage, adherence	Named section	Breadth and depth	Sufficient

Mujuru (2011)	Quasi, pre-post	n/a	Descriptive/ bivariate	USA	Grades 3-5	39% Medicaid	Asthma only	Children and parents	Primary	OAS	n/a	None	Attrition	Integrated	Breadth and depth	Featured, but not sufficient
Pike (2011)	Quasi, pre-post	Class	Descriptive/ bivariate (hypothesis testing)	USA	9-11 years	81% control and 69% intervention African-American; 78% intervention and 86% control FSM	Asthma and non-asthma	Children and teachers	Primary	Multiple session workshop for children	Usual care	None	Dosage	Standalone	Depth, not breadth	Not featured
Richmond (2011)	Quasi, pre-post	n/a	Descriptive/ bivariate	USA	5-10 years	100% African-American, 80% FSM	Asthma only	Children	Primary	Breathe Your Best	n/a	None	Attrition, adherence	Standalone	Neither broad or deep	Not featured
Spencer (2000)	Quasi, pre-post	n/a	Descriptive/ bivariate	USA	6-13 years	34% FSM	Asthma only	Children and parents	Primary	OAS	n/a	None	Adherence	Integrated	Neither broad or deep	Not featured
Splett (2006)	Cluster RCT	School	Multivariate for school absence, narrative otherwise	USA	None	66% African-American; 73% eligible for FSM	Asthma only	Children, with component of enhanced training for school health staff	All	Multiple session workshop for staff, school nurse education	Usual care	None	None	Standalone, Named section (two papers)	Neither broad or deep	Not featured
Terpstra (2012)	Quasi, pre-post	School	Multivariate	USA	Mean: 12 years	44% intervention 56% control Latino; income <$20,000	Asthma only	Children and parents	Junior /Middle	Multiple workshops for children, materials for parents	Equivalent	Social Cognitive Theory	Attrition, dosage, adherence	Integrated	Neither broad or deep	Not featured

Table of 28. Characteristics of included studies: Process Evaluation

Study	Type of Study	Approach*	Process Evaluation Elements
Al-Sheyab 2012	Feasibility	Qualitative	Thematic analysis of student perceptions
Berg 2004	Outcome and process evaluation	Mixed	Thematic analyses of student perceptions
Bignall 2015	Feasibility	Mixed	Thematic analyses of student perceptions
Brasler 2006	Feasibility/case study of implementation	Quantitative data and trialists reports	Implementation challenges and facilitators identified
Bruzzese 2004	Feasibility	Mixed	Section evaluating the intervention reach, dosage and student satisfaction
Bruzzese 2008	Feasibility	Mixed	Standalone section on process evaluation results assessing implementation and student perceptions
Bruzzese 2011	Outcome evaluation with section of process evaluation	Quantitative	Section evaluating the intervention reach (dosage)
Carpenter 2016	Outcome and process evaluation	Mixed	Thematic analyses of student perceptions
Cicutto 2013	Outcome and process evaluation	Mainly quantitative	In addition to information on other processes of interest, provides a description of wider school support through policy changes
Crane 2014	Feasibility	Quantitative	Represented an implementation study through a focus on the impact of changing dosage schedule
Dore-Stites 2007	Feasibility	Quantitative	In addition to information on other processes of interest, provides information on student satisfaction
Engelke 2013	Feasibility	Quantitative	Detailed process/implementation information provided
Gerald 2006	Outcome and process evaluation	Mainly quantitative	In addition to information on other processes of interest, provides a description of implementation challenges
Henry 2004	Outcome and process evaluation	Mainly quantitative	In addition to information on other processes of interest, provides a description of wide school support through policy changes and an assessment of sustainability
Horner 2015	Outcome evaluation with process evaluation information	Quantitative	Includes detailed information on attrition and cost-effectiveness
Howell 2005	Outcome and process evaluation	Quantitative	In addition to information on other processes of interest, provides information on student satisfaction
Jackson 2006	Outcome evaluation with process evaluation information	Quantitative	In addition to information on other processes of interest, provides information on student satisfaction
Joseph 2010	Outcome and process evaluation	Quantitative	In addition to information on other processes of interest, provides detailed information on non-adherence
Joseph 2013	Outcome and process evaluation	Quantitative	Included detailed studies of non-adherence and the relationship with student characteristics
Kintner 2012	Feasibility	Quantitative	In addition to information on other processes of interest, provides information on student satisfaction

Kouba 2012	Outcome evaluation with process evaluation information	Quantitative	In addition to information on other processes of interest, provides detailed information on dosage
Langenfeld 2010	Implementation	Quantitative	In addition to information on other processes of interest, provides detailed information on dosage
Lee 2011	Implementation	Qualitative	In addition to information on other processes of interest, provides detailed information on instructor experiences
Levy 2006	Outcome evaluation with process evaluation information	Quantitative	In addition to information on other processes of interest, provides information on parental adherence to intervention protocol
Magzamen 2008	Outcome evaluation with process evaluation information	Quantitative	In addition to information on other processes of interest, provides information on attrition
McCann 2006	Outcome evaluation with process evaluation information	Quantitative	In addition to information on other processes of interest, provides information on teachers adherence/school-level commitment
Mickel 2016	Outcome and process evaluation	Mixed	Thematic analyses of student perceptions
Mujuru 2011	Outcome and process evaluation	Mainly quantitative	In addition to information on other processes of interest, provides a description of parental satisfaction
Pike 2011	Outcome and process evaluation	Mainly quantitative	In addition to information on other processes of interest, provides information on teachers adherence/school-level commitment
Richmond 2011	Outcome and process evaluation	Mainly quantitative	Includes detailed information on adherence and awareness
Spencer 2000	Outcome and process evaluation	Quantitative	In addition to information on other processes of interest, provides information on instructor satisfaction and school-level commitment
Splett 2006	Outcome and process evaluation	Quantitative	In addition to information on other processes of interest, provides information on adherence and school-level commitment
Terpstra 2012	Outcome and process evaluation	Quantitative	In addition to information on other processes of interest, represents an implementation study through a focus on the impact of parental involvement/increasing parental awareness

***Mixed** = Qualitative and Quantitative

Table 29. Included process evaluation studies: Methodological characteristics and processes described

Results of the search

The first search was conducted in April 2015, and an update search was performed in April 2016. Further searches were conducted in August 2017. Using EPPI-Reviewer software, duplicate studies were identified and removed. Further duplicate studies were identified during the

screening process. The searches for the process evaluation studies were conducted by two members of the review team. The search for the outcome evaluation studies was conducted by the Cochrane trials coordinator, Liz Stovold. After de-duplication, 29,384 titles and abstracts of potential process evaluation studies were screened; 350 title and abstracts were screened for eligibility as outcome evaluations. Following application of inclusion criteria on title and abstract, the remaining 1066 full-text process evaluation records, and 105 full-text outcome evaluation records were assessed independently for eligibility for inclusion. Fifty-four papers, from thirty-three different process evaluation studies were included for further analysis; forty-four papers from thirty-three outcome evaluation studies were also included.

Included Studies

There was little overlap between the studies included in both the process evaluation and outcome evaluation analyses (n = 11 [95, 187, 190, 194, 196, 209-214]). However, Bruzzese 2004 [209] and McCann 2006 [187] did not contribute data to the meta-analyses.

Characteristics of Process Evaluation Studies

Nine studies included evaluations of the effectiveness of Open Airways for Schools (OAS) interventions, or modifications to this programme. OAS includes six 40-minute sessions, aimed at groups of children aged 8-11, who learn different topics including general information about asthma, how to recognise and manage asthma symptoms, and problem solving and decision-making about asthma medication. Other intervention models described included Power Breathing, Staying Healthy-Asthma Responsible and Prepared (SHARP), and Asthma Self-Management for Adolescents (ASMA), although these were common to no more than two included studies.

Across all studies, a diverse curriculum was taught. While most studies mentioned that the intervention developing knowledge and skills around asthma physiology and the monitoring and treatment of symptoms, fewer studies explicitly mentioned that they aimed to develop alliances between children/parents and their care provider(s), although a greater number did involve parents in the intervention in other ways. Most interventions were reliant on trialists, research staff, and others from outside schools to deliver the intervention, however some interventions were

primarily delivered, or supported, pivotally, by school nurses [196, 214-217], teachers [211, 218, 219], or peers [217].

Five of the studies evaluated implementation of interventions involving delivery of self-management education in part or mainly through electronic games or training provided through computers [212, 220-223]. In two of these interventions [220, 221] the information provided was tailored to students based on their input. In total, nine interventions had components where content was tailored towards the needs of an individual child, either through being delivered on a one-to-one basis or through delivering personalised content.

Most of the studies took place in the USA (n = 29), and several of these studies explicitly mentioned that the intervention took place within an urban or inner city area, or explicitly made reference to the diverse socioeconomic or ethnic background. In contrast, two studies specifically explored implementation in rural areas [190, 219]. Fewer studies took place in high schools (n = 14), compared with junior, middle, or elementary/primary schools.

Twenty-one studies collected data before and after the evaluation. Four studies collected post-test data only [189, 207, 209, 224]. Several studies collected data immediately after the intervention or within three-months of the intervention ending. The longest follow-up data collection was 12-months post-test [95, 187, 190, 194, 220, 221]. In fewer studies, the follow-up duration was unclear [189, 207, 214-216, 222, 225].

Evidence that attrition was not problematic was shown in 18 studies. Attrition was substantial in five studies [189, 209, 213, 214, 217], with levels of attrition exceeding over 20% and/or reported by the trial authors as substantial challenge.

Pupil adherence was reported in 21 studies. Evidence that pupil adherence was not problematic was seen in 14 studies. Evidence that adherence was not problematic among other stakeholders was highlighted in six studies [95, 186, 194, 196, 221, 226]. Pupil adherence was problematic in eight studies [189, 212, 213, 217, 220, 223, 227, 228]; these judgements were based on reports from authors, as well as on reports of completion rates of intervention modules and/or completion of evaluation instruments.

Participants received the intended dose of the intervention in nine studies [95, 184, 186-188, 218, 221, 225, 226]. In one study, a dose-response relationship was seen [223]. In seven studies, the

intended dose was not achieved [210, 212, 213, 215, 217, 220, 227], with many children not receiving the intervention. In one study [213], this was based on reports of a shortening of sessions. In another study where parental involvement was an integral component, additional problems in dosage received were reported for caregivers [210]. In one study comparing an individualised intervention model compared to a generic intervention model [220], the individualised model had higher levels of dosage, however both models had fairly low levels of completion of all modules.

Further details of the inclusion criteria for all process evaluation studies is shown in table 28.

Characteristics of Outcome Evaluation Studies

Most of the studies took place in the USA (n = 22), and few studies took place in high schools (n = 8), compared with junior, middle, or elementary/primary schools. There was substantial variation in the intervention model, however nine studies included evaluations of the effectiveness of the OAS, or modifications to this model. There was also variation in the way in which the interventions were delivered. Children received long programmes of sessions in some interventions, with 16 sessions delivered in two studies [190, 191], and 10 sessions [226] and eight sessions [75] in others. Three interventions delivered a single group session to children [187, 212, 213], although the interventions were supported by other activities, including nurse visits or staff training.

Outcome data were collected immediately after the intervention or within three months in a number of studies [75, 191, 209, 210, 212, 213, 229-234], or appeared to be collected alongside the intervention delivery [196]. The longest period between the intervention ending at data collection was 36 months [235] and 24 months [236, 237]. Many studies were included on the basis of study design, however this did not contribute to the meta-analyses as they did not collect the outcomes of interest or did not collect these data in an extractable format (see table 26).

Primary Outcomes

Six outcome evaluation studies provided data that assessed exacerbations leading to hospitalisations, which were combined in meta-analyses [95, 190, 191, 208, 214, 229]. One study also collected this data, however the information was not disaggregated by treatment status [235];

one further study provided data on median hospitalisations, which could not be included in the meta-analyses [213]. Two studies assessed hospitalisations using hospital or school medical records [213, 214]; three studies used parent reports [190, 191, 208]; and two studies used child reports [95, 229]. Most of the studies collected this outcome data after a substantial period of time had elapsed between receipt of the intervention and assessment of the outcome; three studies collected this data after 12 months [95, 190, 208] and one study collected this data after seven months [191]. The remaining two studies collected this data within three months of the intervention.

Asthma symptoms leading to an emergency department visit were collected in 15 outcomes evaluation studies. However, data from Bartholomew *et al* [235] was not used because it was not disaggregated by treatment status. The data from Gerald *et al* [213] was also not included in the meta-analyses as the data collected was not compatible with the rest of the included studies. Three studies used school or hospital records to assess emergency department visits [213, 214, 232]. One study collected this information using tracking sheets completed by the parents [194] and another study used parent interviews [197]. Six further studies using parental self-completion questionnaires [190-192, 195, 208, 212]. The Usherwood symptom questionnaire was used in one study only [235]. Student asthma diaries were used to collect this data in one study [193]; two other studies collected this data from children's reports [95, 229].

Most of the studies that collected information on emergency department visits collected the data after 12 months had passed since receipt of the intervention [95, 190, 192, 194, 195, 197, 208]. One study collected this information after seven months [191]; and 20 weeks in one further study [232]. In three studies, this information was collected within three months of the intervention [212, 214, 229].

Twelve studies assessed school absence or school attendance. Four studies used administrative school records to collect this information [196, 213, 232, 235]. Parent/guardian completed tracking sheets were used in one study [194] and five studies used parent interviews or questionnaires [192, 194, 195, 212, 236]. Tracking sheets completed by school staff were used in one further study [238]. Bruzzese *et al* [95] collected this information directly from the children. One study did not present disaggregated data [235] and was therefore not included in this meta-

analytic model. One additional study [236] presented information on school absences in the form of a risk difference, which was not combined in the meta-analyses, although significant improvements in school absences were seen at three and 12 months. Of the ten studies that were included in the meta-analysis models, seven collected the follow-up data nine months or longer after the intervention [95, 192, 194-197, 238]. In two studies, the follow-up data was collected after three months or less [196, 232], and in one study this information was unclear [213]. Three studies considered any instance of recorded absence from school [192, 194, 195], while the remaining studies measured mean number of days of absence. Most of the studies collected data on any form of absence; one study [238] collected information on school absences related specifically to asthma/respiratory illness.

Days of restricted activity was reported on in three studies [95, 194, 197]. One study used parental recorded tracking sheets/diaries to record days of restricted activity due to asthma [194], one study used parent interviews [197] and one study collected this information directly from the children [95]. All three studies collected this data at 12 months follow-up. Two studies collected data on the mean number of days of restricted activity [95, 197], while one study collected data on any instance of a day of restricted activity [194].

Secondary Outcomes

Five studies reported on unplanned visits to a hospital or GP due to asthma symptoms [95, 192, 194-196]. One study used tracking sheets, completed by parents, to collect this information [194]; two studies used parental questionnaires [192, 195], and one study collected this information directly from children [95]. Administrative records were used in the final study [196].

One study originally collected information on the mean number of unscheduled visits [95], while the remaining studies collected information on any instances of unscheduled visits to a medical provider. All of the studies collected this data after a substantial amount of time had passed since receipt of the intervention. In four studies, this information was collected 9-12 months after the intervention [95, 192, 194, 195]; the final study collected this information longitudinally over a period of six months [196].

Nine studies collected information on day and night-time symptoms [95, 193, 195, 210, 212, 229, 233, 236, 237]. The data from two studies [236, 237] were not included in the meta-analyses as the data was not compatible with the other units of analysis [236], and due to statistical and conceptual differences between post-test and change in post-test outcome data [237]. Among the seven studies included in the meta-analysis, five studies reported on incidence of daytime symptoms [95, 193, 210, 229, 233]; four studies reported on night-time awakenings [95, 195, 210, 212]. Two studies reported on both day and night-time symptoms [95, 210]. Four of the studies reported on intervention effects between six and 12 months after the intervention [95, 193, 195, 233]; the remaining studies collected this information two to three months post-intervention. There was an even split between those studies reporting on the mean level of asthma symptomology occurring in the day/night-time [95, 210, 212, 229], and those focused on measuring any reported incidence of day/night-time symptomology [193, 195, 233].

Lung function information was collected in five studies [75, 190, 193, 233, 238]. One study [238] assessed lung function using peak expiratory flow rate, and focused on the occurrence of poor readings. Spirometry was measured in a second study through the measurement of the percentage predicted change in forced expiratory volume (FEV) over one second [75]. FEV was also used in one further study [233], however this was measured before the use of a bronchodilator. A further study [193] measured peak flow increases as a percentage of pre-test peak (e.g. change in peak flow), and the final study [190] measured airway inflammation. Due to conceptual differences in the outcomes collected, these were not included in the meta-analysis. As shown in table 30, the individual effects extracted showed considerable heterogeneity in the direction and magnitude of effect. This confirmed that meta-analyses were also not possible due to statistical heterogeneity.

Study	Indicator	Collection Point	Mean Cluster Size	ICC Applied*	Data Transformation	Original Effect Size and Standard Error	Final or Transformed Effect Size and Standard Error
Hospitalisations							
Atherly 2009	Hospitalisations in previous 4 weeks	3-months post-intervention	45.8	0.05	Transformed from OR to SMD	OR (0.7736); SE (InOR) (1.385)	SMD (-0.141); SE (0.764)
Bruzzese 2011	Hospitalisations in the past 2 months	12-months post-intervention	N/A	N/A	No	N/A	SMD (-0.219); SE (0.120)
Clark 2005	Hospitalisations	12-months post-intervention	Deemed that analysis methods accounted for clustering	Deemed that analysis methods accounted for clustering	Transformed from OR to SMD	Or (1.43); SE (InOR 0.39)	SMD (-0.197); SE (0.215)
Gerald 2006	Median hospitalisations [not combined]	N/A	N/A	N/A	N/A	N/A	N/A
Horner 2008	Any hospital stays in previous 12 months	7-month follow-up	10.1	0.05	Yes – Transformed from OR to SMD	OR (0.882); SE (InOR) (0.791)	SMD (-0.069); SE (0.436)
Horner 2015	Mean number of hospitalisations since previous data collection	12-month follow-up	8.9	0.05	No	N/A	SMD (-0.057); SE (0.169)
Levy 2006	Mean hospital days	At end of intervention	17.36	0.05	No	N/A	SMD (-0.293); SE (0.174)
Emergency Department Visits							
Atherly 2009	ED visits in previous 4 weeks	3-month follow-up	45.8	0.05	No	N/A	OR (1.036); SE (InOR) (0.916)
Bruzzese 2011	ED visits in previous 2 months	12-month follow-up	N/A	N/A	Yes – Transformed from SMD to OR	SMD (-0.289); SE (0.120)	OR (0.592); SE (InOR) (0.218)
Cicutto 2005	ED visits in the past year	12-month follow-up	9.85	0.05	No	N/A	OR (0.697);

							SE (InOR) (0.407)
Cicutto 2013	ED visits in the past year	12-month follow-up	7.7	0.05	No	N/A	OR (0.318); SE (InOR) ().317)
Clark 2005	ED visits	12-month follow-up	Analysis accounted for clustering	Analysis accounted for clustering	No	N/A	OR (1.002)*; SE (estimated from p-value (InOR)) 0.072
Gerald 2006	Medina ED visits [not combined]	N/A	N/A	N/A	N/A	N/A	N/A
Horner 2008	ED visits in the past year	7-month follow-up	10.1	0.05	No	N/A	OR (0.857); SE (InOR) (0.461)
Horner 2015	Mean number of ED visits since the previous data collection	12-month follow-up	8.9	0.05	Yes – Transformed from SMD to OR	SMD (-0.331); SE (0.578)	OR (0.549); SE (1.049)
Howell 2005	Mean ED visits since previous data collection	12-month follow-up	8.9	0.05	No	N/A	SMD = 0; SE = 0.169
Levy 2006	Mean ED visits	Duration unclear	17.36	0.05	No	N/A	SMD = -0.286; SE = 0.174
McGhan 2003	Any ED visits in past year	9-month follow-up	9	0.05	Transformed from OR to SMD	OR = 1.283; SE (InOR) = 0.649	SMD = 0.1375; SE = 0.358
McGhan 2010	Any ED visits in past year	12- month follow-up	8.3	0.05	Transformed from OR to SMD	OR = 2.64; SE (InOR) = 0.707	SMD = 0.537; SE = 0.390
Persaud 1996	ED visits in 20 weeks period post-intervention	Post intervention	N/A	N/A	Transformed from OR to SMD	OR = 0.286; SE (InOR) = 0.737	SMD = -0.691; SE = 0.407
Velsor-Friedrich 2005	Any urgent doctor visits in previous 12 months	12-month follow-up	13	0.05	Transformed from OR to SMD	OR = 0.683; SE (InOR) = 0.933	SMD = -0.252; SE = 0.515
School Absences							
Bruzzese 2011	Mean absence in previous 2 weeks	12-month follow-up	N/A	N/A	No	N/A	SMD = -0.382; SE = 0.121
Cicutto 2005	Any absence over a year	12-month follow-up	9.85	0.05	No	N/A	SMD = -0.256; SE – 0.151

Cicutto 2013	Any absence over a year	12-month follow-up	7.7	0.05	Transformed from OR to SMD	OR = 0.660; SE (InOR) = 0.129	SMD = -0.229; SE = 0.071
Gerald 2006	Absence recorded on school records	Duration unclear	Analysis methods accounted for clustering	Analysis methods accounted for clustering	No	N/A	SMD = -0.199; SE = 0.084
Gerald 2009	Absence from school due to asthma/respiratory illness	15-month follow-up	N/A	N/A	Transformed from OR to SMD	OR = 1.1667; SE (InOR) = 0.364	SMD = 0.085; SE = 0.227
Howell 2005	School days missed in previous 6 weeks	3-month follow-up	3.25	0.05	No	N/A	SMD = 0.152; SE = 0.635
McGhan 2003	Any missed school days in previous 12 months	12-month follow-up	8.3	0.05	Transformed from OR to SMD	OR = 0.640; SE (InOR) = 0.353	SMD = 0.246; SE = 0.195
McGhan 2010	Mean absence in previous 2 weeks	12-month follow-up	N/A	N/A	No	N/A	SMD = -0.382; SE = 0.121
Persaud 1996	Mean school absence on school records	Immediately after intervention	N/A	N/A	No	N/A	SMD = -0.236; SE = 0.335
Splett 2006	Mean percentage of days attended	12-month follow-up	Analysis methods accounted for clustering	Analysis methods accounted for clustering	No	N/A	SMD = 0.019; SE = 0.051
Days of Restricted Activity							
Bruzzese 2011	Mean self-reported days of restricted activity in previous 2 weeks	12-month follow-up	N/A	N/A	No	N/A	SMD = -0.349; SE = 0.120
Cicutto 2005	Days of restricted activity due to asthma	12-month follow-up	9.85	0.05	No	N/A	SMD = -0.318; SE = 0.151
Cicutto 2013	Percentage of students reporting days of restricted activity	12-month follow-up	7.7	0.05	Analysis methods accounted for clustering	OR = 0.612; SE (InOR) = 0.130	SMD = -0.271; SE = 0.072

Unplanned Visits to Medical Providers							
Bruzzese 2011	Mean acute care visits in the previous 2 months	12-month follow-up	N/A	N/A	Transformed from SMD ratio to OR	SMD = -0.283; SE = 0.120	OR = 0.598; SE = 0.217
Cicutto 2013	Unscheduled care in the past year	12-month follow-up	7.7	0.05	No	OR = 0.703; SE (InOR) = 0.143	SMD = -0.194; SE = 0.079
McGhan 2003	Any unscheduled doctor visits	9-month follow-up	9	0.05	No	OR = 0.886; SE (InOR) = 0.426	SMD = -0.067; SE = 0.235
McGhan 2010	Any unscheduled GP visits over previous 12 months	12-month follow-up	8.3	0.05	No	OR = 1.169; SE (InOR) = 0.397	SMD = 0.086; SE – 0.219
Splett 2006	Episodic asthma to school health office	Over 6 months following start of interventi on	97.6	0.05	No	OR = 0.913; SE (InOR) = 0.282	SMD = -0.046; SE = 0.156
Daytime Symptoms							
Atherly 2009	Mean days with asthma symptoms	3-month follow-up	45.8	0.05	No	N/A	SMD = -0.026; SE = 0.168
Bruzzese 2008	Mean days with symptoms in previous 2 weeks	2-month follow-up	45.8	0.05	No	N/A	SMD = -0.026; SE = 0.168
Bruzzese 2011	Mean days in previous 2 weeks with asthma symptoms	12-month follow-up	N/A	N/A	No	N/A	SMD = -0.210; SE = 0.120
Shah 2001	Number of students reporting attacks in school at follow-up	6-month follow-up	41.8	0.05	Transformed from OR to SMD	OR = 0.647; SE (InOR) = 0.488	SMD = -0.240; SE = 0.269
Velsor-Friedrich 2005	Symptom days in previous 2 weeks	12-month follow-up	13	0.05	Transformed from OR to SMD	OR = 0.846; SE (InOR) = 0.705	SMD = -0.030; SE = 0.413
Night-time Symptoms							
Bruzzese 2008	Mean night awakenings in previous 2 weeks	2-month follow-up	N/A	N/A	No	N/A	SMD = -0.433; SE = 0.423
Bruzzese 2011	Mean self-reported night-time awakenings in previous 2 weeks	12-month follow-up	N/A	N/A	No	N/A	SMD = -0.388; SE = 0.121

Howell 2005	Mean night-time awakenings in previous 6 weeks	3-month follow-up	4.25	0.05	No	N/A	SMD = 0.253; SE = 0.478
McGhan 2003	Two or more night-time awakenings in previous 2 weeks	9-month follow-up	9	0.05	Transformed from OR to SMD	OR = 1.237; SE (InOR) = 0.412	SMD = 0.117; SE = 0.227
Use of Reliever Therapies							
Gerald 2009	Rescue medication use over twice a week	15-month follow-up	N/A	N/A	N/A	OR = 0.228; SE (InOR) = 0.582	N/A
McGhan 2003	Number of students with appropriate use of reliever medication	9-month follow-up	9	0.05	N/A	OR = 3.48; SE (InOR) = 0.565	N/A
McGhan 2010	Use of SABA in previous 2 weeks	12-month follow-up	8.3	0.05	N/A	OR = 0.878; SE (InOR) = 0.356	N/A
Splett 2006	Students with access to reliever medication visiting health office	Over 6 months following start of interventi on	97.6	0.05	N/A	OR = 1.28; SE (InOR) = 0.282	N/A
Use of Corticosteroids and/or Add-on Therapies							
Bruzzese 2011	Use of controller medication	12-month follow-up	N/A	N/A	No	N/A	OR = 1.451; SE (InOR) = 0.240
Horner 2015	ICS adherence	5-month follow-up	8.9	0.05	No	N/A	SMD = -0.605; SE = 0.173
Howell 2005	ICS adherence as prescribed during previous week	3-month follow-up	4.25	0.05	No	N/A	SMD = 0.953; SE = 0.546
McGhan 2003	Currently using ICS	9-month follow-up	9	0.05	No	N/A	OR = 1.112; SE (InOR) = 0.418
McGhan 2010	Currently using ICS	12-month follow-up	8.3	0.05	No	N/A	OR = 0.962; SE (InOR) = 0.376
Splett 2006	Students with controller medication visiting health office	Over 6 months following start of interventi on	97.6	0.05	N/A	OR = 1.703; SE (InOR) = 0.806	SMD = 0.293; SE = 0.445
Lung Function							

Gerald 2009	Poor peak flow measures (red/amber readings)	15-month follow-up	N/A	N/A	No	OR = 0.94; SE (InOR) = 0.334	OR = 0.94; SE (InOR) = 0.334
Horner 2015	Airway inflammation	12-month follow-up	8.9	0.05	No	N/A	SMD = -0.011; SE = 0.169
Shah 2001	FEV_1: FVC before bronchodilator	3-month follow-up	Analysis methods accounted for clustering	Analysis methods accounted for clustering	No	N/A	SMD = 0.074; SE = 0.127
Patterson 2005	FEV_1 (percentage predicted change)	2-month follow-up	Analysis methods accounted for clustering	Analysis methods accounted for clustering	No	N/A	SMD = -0.05; SE = 0.177
Velsor-Friedrich 2005	Peak flow increases as a percentage of pre-test peak flow (change)	12-month follow-up	13	0.05	No	N/A	SMD = -5.905; SE = 0.839
Health-Related Quality of Life							
Al-Sheyab 2012	Arabic PAQLQ	3-month follow-up	Analysis methods accounted for clustering	Analysis methods accounted for clustering	No	N/A	SMD = 0.299; SE = 0.129
Cicutto 2005	Juniper PAQLQ overall QoL	2-month follow-up	9.85	0.05	No	N/A	SMD = 0.356; SE = 0.151
Cicutto 2013	Juniper PAQLQ overall QoL	12-month follow-up	7.7	0.05	No	N/A	SMD = 0.308; SE = 0.064
Henry 2004	Juniper PAQLQ overall QoL	6-month follow-up	15.2	0.05	No	N/A	SMD = 0.128; SE = 0.114
Horner 2008	Juniper PAQLQ overall QoL	7-month follow-up	10.2	0.05	No	N/A	SMD = 0.083; SE – 0.196
Howell 2005	Juniper PAQLQ overall QoL	3-month follow-up	6	0.05	No	N/A	SMD = 0.020; SE = 0.484
Kintner 2009	Participation in life activities scale	Immediately post-intervention	Analysis methods accounted for clustering	Analysis methods accounted for clustering	No	N/A	SMD = 0.583; SE = 0.263

Patterson 2005	Change in Juniper PAQLQ overall QoL	Change in QoL between baseline and 4 months post-intervention	Analysis methods accounted for clustering	Analysis methods accounted for clustering	No	N/A	SMD = 0.064; SE = 0.152
Shah 2001	Juniper PAQLQ overall QoL; percentage of students with clinically significant improvements	3-month follow-up	Analysis methods accounted for clustering	Analysis methods accounted for clustering	No	N/A	SMD = 0.470; SE = 0.187
			Withdrawal				
Al-Sheyab 2012	Withdrew between baseline and outcome collection	3-month follow-up	65.25	0.05	No	N/A	OR = 0.511; SE (InOR) = 1.074
Bartholomew 2006	Lost to follow-up at post-test	Duration unclear	11.2	0.05	No	N/A	OR = 0.237; Se (InOR) = 0.145
Bruzzese 2008	Withdrew between baseline and outcome collection	Immediately post-intervention	N/A	N/A	No	N/A	OR = 0.307; SE (InOR) = 1.683
Bruzzese 2011	Withdrew between baseline and outcome collection	12-month follow-up	N/A	N/A	No	N/A	OR = 1.313; SE (InOR) = 0.279
Cicutto 2005	Withdrew between baseline and outcome collection	6-month follow-up	9.85	0.05	No	N/A	OR = 1.788; SE (InOR) = 0.629
Gerald 2009	Withdrew between baseline and outcome collection	6-month follow-up	N/A	N/A	No	N/A	OR = 1.788; SE (InOR) = 0.613
Horner 2008	Withdrew between baseline and outcome collection	7-month follow-up	10.2	0.05	No	N/A	OR = 1.333; SE (InOR) = 0.531
Horner 2015	Failed to complete final data collection	12-month follow-up	8.9	0.05	No	N/A	OR = 0.75; SE InOR) = 0.486
Kintner 2009	Withdrew during intervention and between completion and follow-up	12-month follow-up	13.2	0.05	No	N/A	OR = 30.176; SE (InOR) = 1.860

Levy 2006	Failure to complete outcome evaluation	12-month follow-up	17.36	0.05	No	N/A	OR = 0.357; SE (InOR) = 0.3881
McGhan 2003	Withdrew between baseline and outcome collection	9-month follow-up	9	0.05	No	N/A	OR = 1.147; SE (InOR) = 0.5381
McGhan 2010	Withdrew between baseline and interim outcome collection	6-month follow-up	8.3	0.05	No	N/A	OR = 1.007; Se (InOR) = 0.387
Patterson 2005	Withdrew during intervention	Post-intervention (immediately following intervention)	7.95	0.05	No	N/A	OR = 5.675; SE (InOR) = 1.087
Shah 2001	Withdrew between baseline and outcome collection	3-month follow-up	45.3	0.05	No	N/A	OR = 1.343; SE (InOR) = 0.475

*ICC = Intracluster Correlation Coefficient

Table 30. Details of data transformations and adjustments made for meta-analyses

Four outcome evaluation studies assessed uses of reliever therapies [192, 195, 196, 238]. Two studies reported on the use of rescue mediation [238] and short-acting bronchodilators [192], respectively. Both of these studies measured long-term intervention effects at twelve [192] and fifteen months [238] and were considered similar enough to combine in a meta-analysis. The remaining two studies measured appropriate use of reliever medication [195] and access to reliever medication [196]. Due to conceptual differences in the way in which the use of reliever therapies were measured among the studies, information from just two studies were included in the meta-analyses [192, 238]. Information from the other two studies can be found in table 30.

Corticosteroid usage and dosage was measured in six studies [95, 190, 192, 195, 196, 212]. One study measured whether students had access to controlled medication while visiting the school health office [196]. Two further studies measures whether children were adhering to guidance provided around correct corticosteroid usage [190, 212]. Three of the studies measured any reported use of corticosteroid or controller medication [95, 192, 195]. Data from these studies were analysed separately as adherence [190, 212] was considered to differ conceptually from usage [95, 192, 195]. Two studies [190, 212] collected information from children at five and three months, respectively, in the meta-analysis of adherence. All three studies in the second meta-analysis on medication usage collected information either nine or 12-months post-intervention. Data from all six studies are shown in table 30.

Health-related quality of life was measured in 12 outcome evaluation studies. The data from three studies [187, 192, 237] were not presented in a way that could be extracted, the data from one further study [75] measured change in quality of life and one study [233] measured clinically significant improvements. In the nine studies that had an effect size, eight were based on the Juniper Paediatric Quality of Life Questionnaire overall Quality of Life [239]. An Arabic version of this questionnaire was used in one study [207]. Kintner *et al* [230] measured quality of life through responses to the participation in life activities scale.

Two sets of meta-analyses were conducted for a model measuring changes in quality of life. One of these used effect sizes calculated through SMDs, to allow data from Kintner *et al* [230] to be included. A second model of mean differences was conducted to allow the incorporation of data from two studies [75, 233], which collected data on change scores. Therefore, data from six

studies was common to both models. Quality of life was measured within four months of the intervention in most of the studies. Two studies collected this information at six to seven months after the intervention [191, 211] and one study collected data 12 months after the intervention [194].

Withdrawal data was frequently presented, however not always in a format that could be extracted to form an effect size. Often, this was due to studies reporting overall numbers lost in the study without disaggregating by treatment arm [193, 194] or studies reporting no losses [232]. Fourteen studies provided enough data for an effect size (odds ratio) to be calculated. Few studies reported on active withdrawal processes occurring during the intervention, but reported on a failure to collect children's data at follow-up instead. Data were collected at different points between the intervention and follow-up, including at four months or less [75, 207, 210, 233], at six to seven months [191, 192, 197, 238], and at nine to twelve months [95, 190, 195, 214, 230]. One study had an unclear duration [235].

Excluded Studies

From the title and abstract screening, 28,318 records were excluded for being outside of the remit of the review of process evaluations. Following full-text screening, 1029 records were excluded, with reasons detailed in the PRISMA diagram in figure 20 from the review of process evaluation studies. Based on title and abstract screening, 274 records were excluded as being outside of the remit of the review of outcome evaluation studies. Following full-text screening, a further 67 records were excluded, and the reasons are detailed in the PRISMA diagram in figure 21 from the outcome evaluation studies.

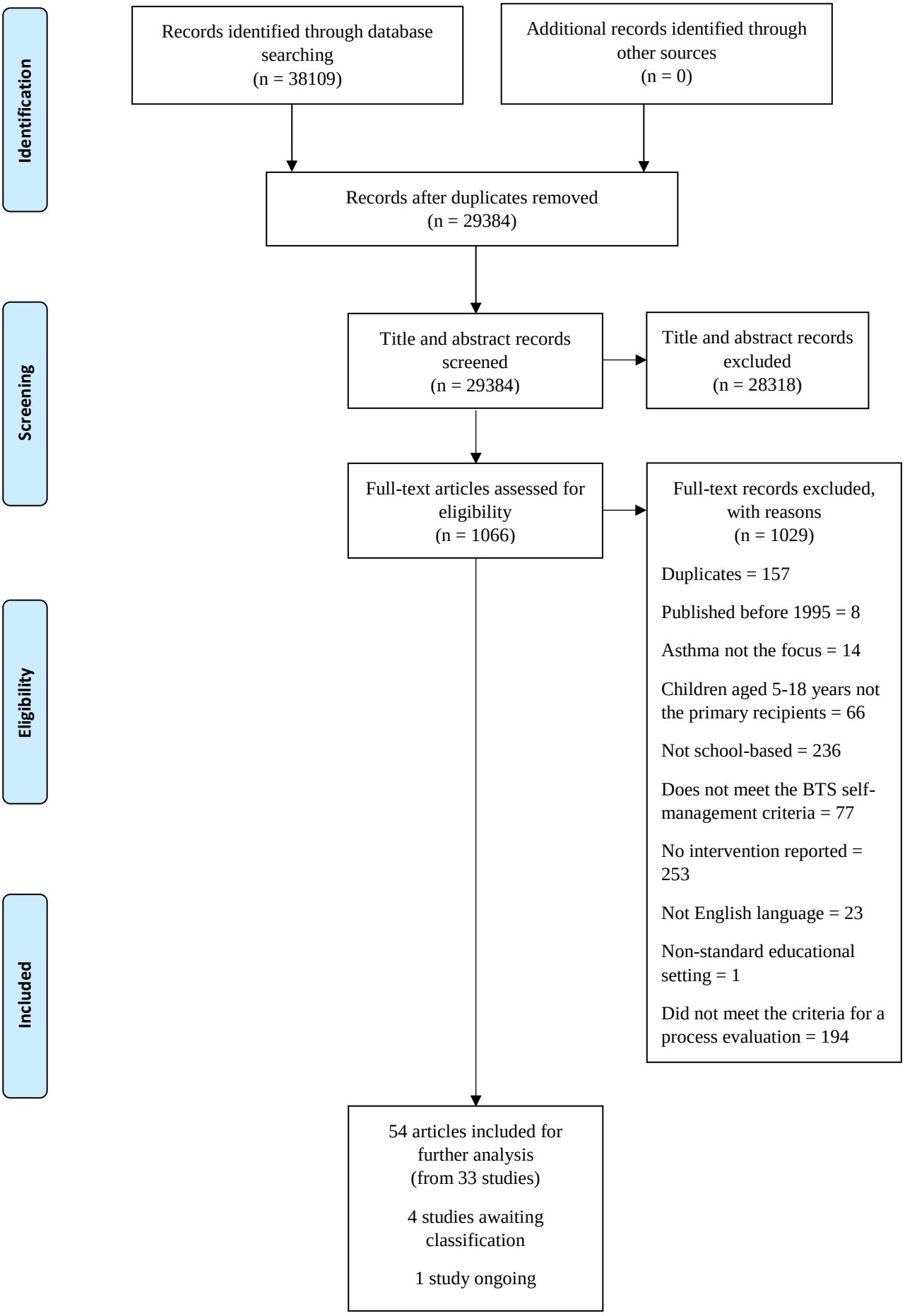


Figure 20. PRISMA diagram for process evaluation studies

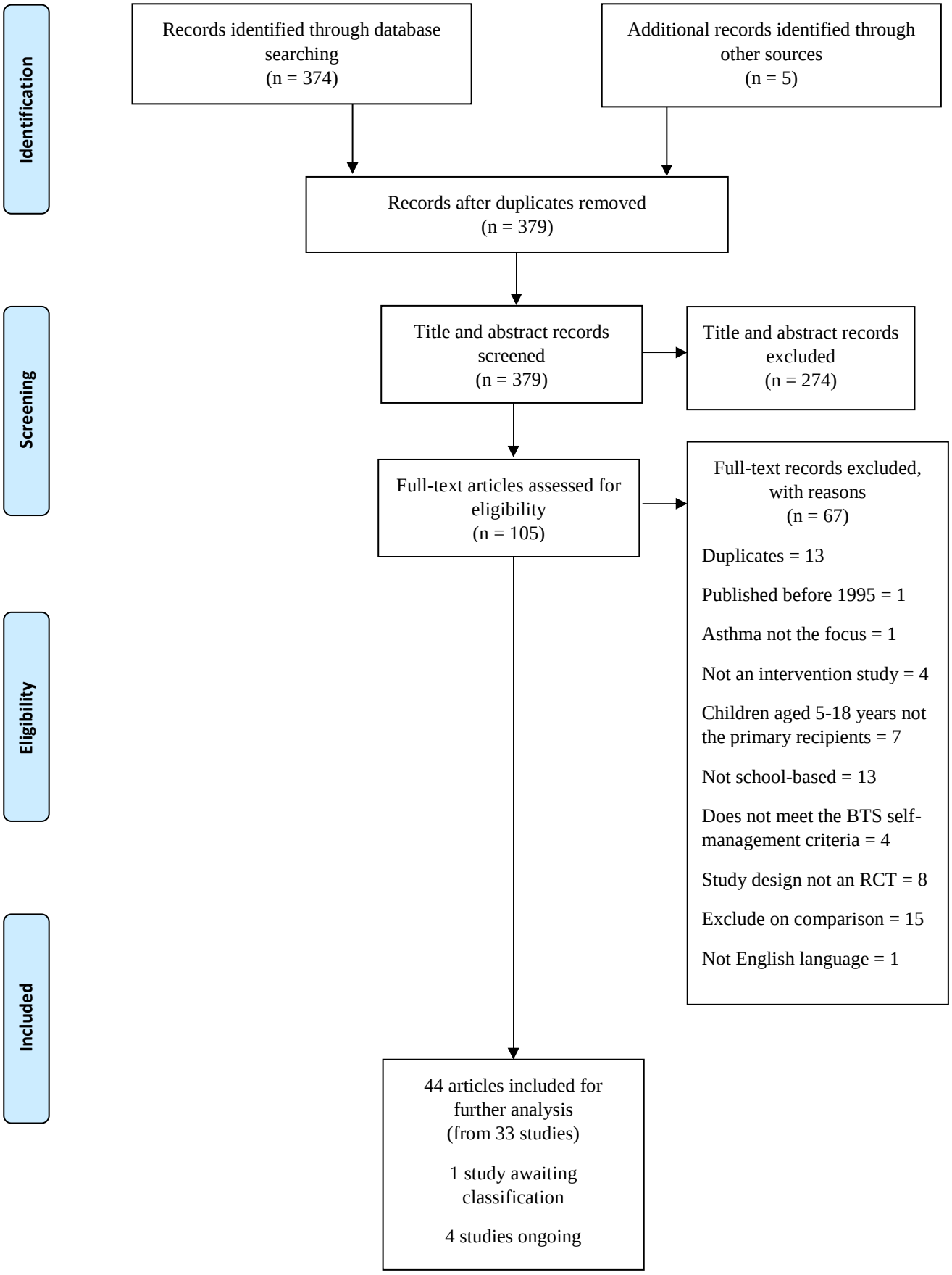


Figure 21. PRISMA diagram for outcome evaluation studies

5.4.2 Risk of Bias in Included Studies

The risk of bias judgements are shown in figure 22 as percentages across each of the risk of bias domains.

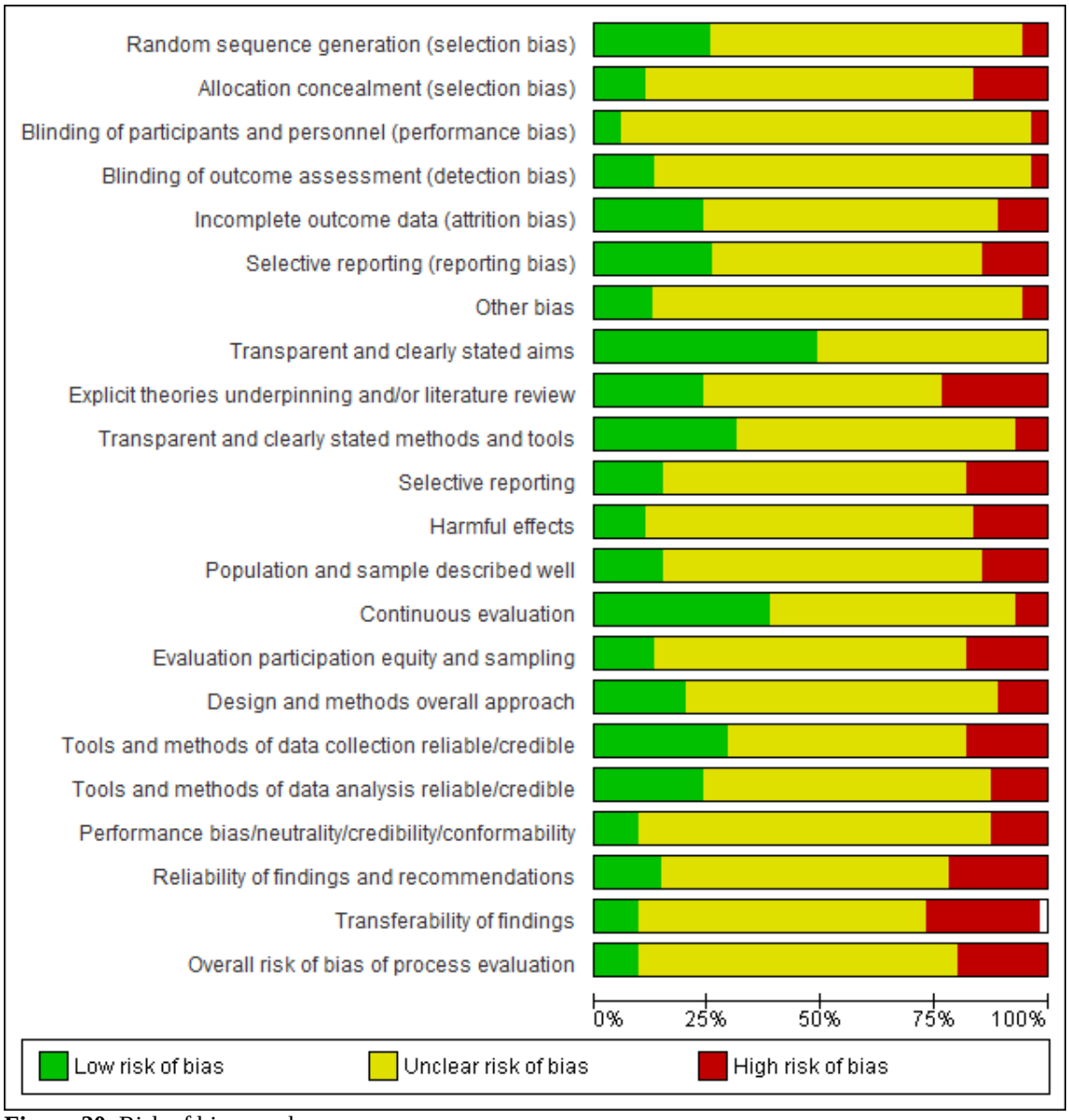


Figure 20. Risk of bias graph

Process Evaluation Studies

The quality of the process evaluation studies was assessed across five areas:

i. Transparent and clearly stated aims (0 high; 27 low; 6 unclear)

ii. Explicit theories underpinning the intervention (10 high; 14 low; 9 unclear)

iii. Transparent and clearly stated methods and tools (4 high; 17 low; 12 unclear)

iv. Selective reporting (10 high; 8 low; 15 unclear)

v. Harmful effects (8 high; 5 low; 20 unclear)

Population and selection factors were assessed across four areas:

i. Population and sample described well (8 high; 8 low; 17 unclear)

ii. Continuous evaluation (3 high; 8 low; 22 unclear)

iii. Evaluation participation equity and sampling (9 high; 7 low; 17 unclear)

iv. Design and methods overall approach (6 high; 10 low; 16 unclear)

Reliability and transferability of the findings were assessed across two areas:

i. Reliability of findings and recommendations (11 high; 8 low; 14 unclear)

ii. Transferability of the findings (13 high; 5 low; 15 unclear)

Overall risk of bias for the process evaluation studies included 10 high risk studies, five low risk studies and 18 unclear

Outcome Evaluation Studies

In five studies, allocation concealment generated a low risk of bias decision [95, 194, 197, 233, 238]. In eight outcome evaluation studies, the allocation concealment risk of bias was high [191, 192, 212, 214, 230, 231, 237, 240].

Blinding of participants and personnel generated a low risk of bias in three studies [190, 194, 214]; a high risk of bias was seen in two studies [191, 230]. Seven studies recorded a low risk of bias for blinding of outcome assessment [95, 190, 194, 197, 214, 230, 232]; two studies yielded a high risk of bias for blinding of outcome assessment [234, 237].

A low risk of bias for incomplete outcome data was seen in seventeen studies. A high risk of bias was seen in seven studies [192, 195, 209, 214, 229, 235, 241].

Selective reporting was low in twenty studies. In twelve studies, selective reporting yielded a high risk of bias.

Other Potential Sources of Bias

Missing data recorded a low risk of bias in thirteen studies, and a high risk of bias in seven studies [192, 197, 209, 212, 214, 235, 242].

A low risk of bias for baseline imbalance was seen in fifteen studies; a high risk of bias was seen in six studies [187, 195, 207, 212, 229, 237].

Risk of contamination was low in twenty-nine studies. In five studies, a high risk of bias was seen [209, 210, 232, 234, 238].

5.4.3 Part 1: QCA of Determinant Conditions for Successful Intervention Implementation

Across the 27 included studies, eight had high implementation scores on the combined outcome (attrition, adherence and dosage), and were considered as being mainly or fully in a set of studies marked as being successfully implemented [95, 207, 210, 211, 221, 224-226]. Eight studies had low implementation success scores and were identified as being mainly or entirely out of the successfully implemented set of studies [209, 212, 213, 215, 217, 223, 227, 228]. The remaining studies had higher levels of missing data or conflicting results, therefore their implementation success was unclear.

In many of the studies with lower implementation success, the difficulty of building an intervention into the school curriculum and into pupil's schedules were viewed as undermining the intervention [209, 212, 213, 223, 227]. Additional factors included difficulties with high staff turnover [213]; high pupil turnover and/or chaotic families [212, 227] and low student motivation, particularly in the absence of incentives [217]. Varied explanations were also seen for successful implementation. These included high levels of school commitment [211, 226]; high levels of student and teacher motivation [207, 224]; the development of group cohesion [210]; tailoring of messages to pupils [95, 220]; and additional communications with parents [225]. Table 31 shows a summary of the QCA findings.

Model 1	School Health Centre	High School	Parent Intervention Recipients	Teachers Intervention Recipients	Others Intervention Recipients		Successful Intervention
1	✓	✓	✓	x	x		✓
2	x	✓	x	-	-		✓
3	x	-	x	x	x		✓
Model 2	**Additional marketing materials**	**Incentives**	**Catch-up Sessions**	**Reminders**			**Successful Intervention**
	-	-	-	-	-		No combinations
Model 3	**Alliances with care providers**	**Symptom recognition or management**	**Tailored content**	**Personal responsibility**	**Interactive pedagogical style**	**Diverse pedagogical style**	**Successful Intervention**
	-	-	-	-	-		No combinations
Model 4	**Theory driven**	**Run in class time**	**Run in free time**	**School nurse involved in delivery or teaching**	**Personalised or individual one-to-one teaching**		**Successful Intervention**
1	✓	-	x	x	-		✓
2	✓	-	-	✓	x		✓
Model 5	**School asthma policy**	**Child satisfaction**	**Teacher engagement**	**Parent engagement**	**School nurse engagement**		**Successful Intervention**
1	x	-	-	✓	x		✓
2	-	✓	-	-	x		✓
Model 6	**Theory driven**	**Run in free time**	**Child satisfaction**	**Parents engaged**	**High school**		**Successful Intervention**
1	✓	-	✓	-	✓		✓
2	✓	-	-	✓	✓		✓
3	✓	x	-	-	✓		✓
4	✓	x	✓	✓	-		✓

✓ = Condition needs to be present; x = condition needs to be absent; - = Condition not important

Table 31. Summary of QCA Results

For each model, an indicator of consistency and coverage was created, according to the level of certainty that the combination triggered the outcome, and according to how much of the outcome was explained by the combination. Different areas of implementation were first explored separately, before bringing the evidence together in the final model (model six). This strategy was mainly due to limited diversity, where too many possible combinations of characteristics were not supported by studies. No combinations of characteristics were found to consistently trigger successful implementation, with respect to recruitment and retention (model two), and pedagogical factors (model three). The data and truth tables for the models below can be found in appendix 12.

Model One: Setting and Participant Characteristics

Included within this model were the presence of existing health facilities within schools (e.g. a school nurse or first aider), the type of school, whether teachers or other school personnel (including school nurses) received additional training, and whether parents received the intervention. Three essential pathways were identified to running a successful intervention, of which, two suggested different ways of running a successful intervention in a high school. In the first pathway, which was supported by evidence from two studies [207, 211], successful interventions were seen where there was no school-based health facilities (e.g. a school nurse/nurses office) and no direct involvement from parents. However, evidence from two other studies [210, 225] suggested that interventions were successful where there were school-based health facilities and direct parental involvement, but no additional training for teachers. Two further pathways were also identified. The first of these (inessential) suggested that, where interventions took place away from high schools (e.g. junior/middle school), additional teacher training, and training for other stakeholders, were enough to generate a successful outcome. A second (essential) pathway suggested that, regardless of whether or not the intervention took place in a high school, no health facilities within the school, and no additional training for teachers and stakeholders, as well as no additional parental involvement, were sufficient to generate an outcome.

Model Two: Recruitment and Retention Processes

A truth table was attempted to explore the possible number of conditions that contributed to successful implementation, based on recruitment and retention processes. This focussed on the use of incentives, marketing materials, reminders and providing make-up sessions. However, no configurations were found that were potential subsets of the outcome. Therefore, these were not included in the final consolidated model.

Model Three: Curriculum, Pedagogy and Intervention Emphasis

A model exploring the impact of the curriculum content, pedagogical (teaching) style, and description of the emphasis of the intervention was developed, however no configuration showed sufficient levels of consistency. Therefore, these components were not included in the final consolidated model.

Model Four: Further Modifiable Intervention Design Features

The first condition in this model reflected the extent to which the authors reported that their interventions included a named theoretical framework, which underpinned the intervention. Two conditions reflected whether the students own time was interrupted (e.g. the intervention was conducted during lunchtime or after school) or whether the intervention was delivered during their normal lessons. A condition was also included which reflected the extent to which the intervention was delivered, or facilitated, by a school nurse. This was to establish the importance of having medical personnel involved in the intervention, as a condition for successful implementation. It was hypothesised that running personalised or individualised sessions may reduce the ability of trialists to successfully deliver an intervention, as it may be difficult to balance individualised sessions across a larger cohort of students.

The intermediate solution confirmed the importance of the intervention being theory driven, and two pathways were identified. The first pathway suggested that a school nurse is needed for successful implementation if the intervention does not involve personalised or individualised sessions. The second pathway, however, suggested that, where interventions are provided outside of students' free time (e.g. during lesson time), successful implementation is achieved when a school nurse is not involved.

Model Five: Stakeholder Involvement and Engagement

Levels of stakeholder involvement and engagement was explored across the school level (through the development of school policies for asthma), the child level (through measuring satisfaction) and at the levels of other stakeholders (through exploring teacher, parent and school nurse engagement). These conditions reflected whether instances of problematic or enthusiastic engagement were reported. The intermediate solution showed two essential pathways which were sufficient to produce a positive outcome. One of these pathways included child satisfaction, and the other pathway included reporting good levels of engagement with parents, however these were only sufficient when in the presence, or absence, of other conditions. Each of these pathways had high levels of consistency, which suggested sufficient configurations, however individual pathways showed low levels of coverage.

Model Six: Final Consolidated Model

In the consolidated model, priority was given to the conditions that were part of combinations with high consistency and coverage scores, and evidence from models one, four and five were used, to understand some of the important conditions to consider when designing an intervention. Based on the raw data in table 32, a truth table was created (table 33) which showed the extent to which sets of studies with certain combinations of conditions overlapped with a set of studies in the successful intervention set.

	Successful Intervention	High School	Child Satisfaction	Theory Driven	Took Place in Students' Free Time	Good Engagement with Parents
Joseph 2010	0.52	1	0	1	0.33	0
Kouba 2012	0.33	1	0	1	1	0
Dore-Stites 2007	0.67	0	1	1	0.33	0.75
Joseph 2013	1.00	1	0	1	0.75	1
Mujuru 2011	0.67	0	0	0	0	0.25
Henry 2004	0.83	1	0	0	0	0
Pike 2011	0.67	0	0	0	0	0
Spencer 2000	0.33	0	0	0	0.33	1
Engelke 2013	0.50	0.5	0	0	0.33	1
Splett 2006	0.50	0.5	0	0	0.33	0
Kintner 2012	0.83	1	1	1	1	0.25
Berg 2004	0.83	1	1	1	0.33	0
Howell 2005	0.33	0	1	1	0.33	0.75
Gerald 2006	0.33	0	0	0	0.33	0
Langenfeld 2010	0.33	0	0	0	0.33	0
Al-Sheyab 2012	0.83	1	1	1	0.33	0
Levy 2006	0.52	0	0	0	0.3	0
Terpstra 2012	1.00	0.66	1	1	1	0.25
Horner 2015	0.67	0	1	1	1	0
Bruzzese 2008	0.94	0.66	1	1	0.33	1
Lee 2011	0.50	0	1	1	0	0
Bruzzese 2004	0.33	1	1	1	0.75	0
Cicutto 2013	0.67	0	1	1	1	0
Brasler 2006	0.00	0.66	0	0	0.75	0
Crane 2014	0.50	0	1	1	1	0
Bruzzese 2011	0.88	1	1	1	0.33	0
Magzamen 2008	0.19	0.75	0	0	1	0

Table 32. Data table for QCA model 6: Consolidated model

High School	Child Satisfaction	Theory Driven	Students' Free Time	Good Parent Engagement	Outcome Code (based on consistency score)	Studies with Membership in Causal Combination >0.5	Consistency Score with Subset Relationship	Proportional Reduction in Inconsistency	Cases
1	1	1	0	0	1	2	1	1	Al-Sheyab 2012; Berg 2004
1	0	1	1	1	1	1	1	1	Joseph 2013
1	1	1	0	1	1	1	1	1	Bruzzese 2008
1	0	1	0	0	1	2	0.924	0.841	Bruzzese 2011; Joseph 2010
1	1	1	1	0	1	2	0.853	0.752	Bruzzese 2004; Kintner 2012
0	1	1	0	1	1	2	0.815	0.668	Dore-Stites 2007; Howell 2005
1	0	1	1	0	0	2	0.768	0.595	Kouba 2012; Terpstra 2012
0	0	0	0	1	0	1	0.763	0	Engelke 2013; Spencer 2000
1	0	0	0	0	0	1	0.762	0.615	Henry 2004
0	0	1	1	0	0	3	0.675	0.463	Cicutto 2013; Crane 2014; Horner 2015
0	0	0	0	0	0	5	0.67	0.322	Gerald 2006; Langenfeld 2010; Levy 2006; Mujuru 2011; Pike 2011; Splett 2006
0	0	1	0	0	0	1	0.6	0	Lee 2011
1	0	0	1	0	0	1	0.358	0	Magzamen 2008
1	1	0	1	0	0	1	0	0	Brasler 2006

Table 33. Truth table for QCA model 6: Consolidated model

Four combinations of conditions were found to trigger the outcome. The solution emphasises the importance of being theory-driven across all settings for an intervention to be successfully implemented. Three of these pathways were specific to high schools. Here, the evidence suggests that in addition to being theory-based, having good levels of engagement with parents, or having high levels of child satisfaction, as well as running the intervention outside the students' own time lead to a successfully implemented intervention. A pathway that was not specific to high schools also reinforces these findings, and found that being theory-based, fostering high levels of student satisfaction, reporting good levels of parental engagement, and running an intervention outside the students' own time are sufficient conditions for triggering a positive outcome.

These pathways had a consistency score of 0.862, which suggested that they were sufficient to achieve the outcome. Interventions that are designed with these sets of characteristics are therefore likely to be successfully implemented. No evidence was found for whether any of the combinations also predicted the negation of the outcome. However, a modest coverage score of 0.432 suggests that other pathways also exist in triggering successful implementation.

Based on the results of the QCA analyses, the following conditions were intended to be included in the meta-analyses, either as subgroup analyses or as covariates in meta-regression:

i. Type of school: High; primary/elementary; junior/middle; other
ii. Theory-driven: Does the study name a theoretical framework which underpins the intervention design or delivery style?
iii. Parental engagement: Did parents engage or participate in the way in which they were expected?
iv. Child satisfaction: Did at least 75% of children report satisfaction with the intervention, or did the study authors report high levels of satisfaction?
v. Timing of the intervention: Does the intervention interfere with the child's free time?

However, due to data constraints, child satisfaction could not be explored in the meta-analyses, as very few studies collected this information. Parental engagement was also included as parental involvement (i.e. whether parents were actively included in the intervention) for similar reasons.

5.4.3 Part 2: Meta-Analyses of Effectiveness

Meta-analyses were presented for eleven outcomes. The main comparison explored the effect of school-based asthma interventions compared with usual care. For each outcome, the effect sizes for each of the pre-specified subgroup analyses were presented. These included school type, age of children, SES of the children, and the main instructor, which reflected whether school staff were involved in the delivery of the intervention.

Where heterogeneity was seen, additional subgroup analyses were conducted, based on the results of the QCA. Additional sensitivity analyses were also conducted.

Primary Outcome One: Exacerbations leading to hospitalisation

Effect sizes were extracted from seven studies [95, 190, 191, 208, 213, 214, 229], six of which were included in the meta-analysis. The evidence showed that school-based self-management interventions for children with asthma were effective in reducing levels of hospitalisations among children ((SMD -0.19, 95% CI -0.35 to -0.04); figure 23). The effect sizes from all six studies were in the same direction, and the I^2 and Q-statistic values provided no evidence of statistical heterogeneity.

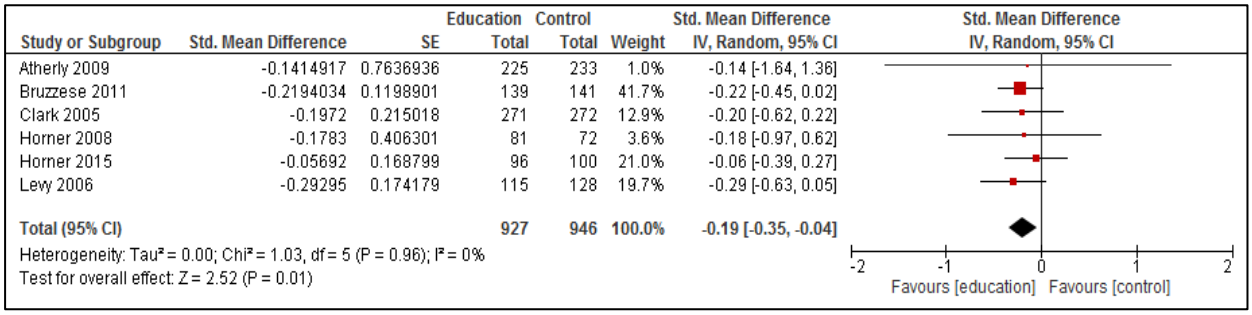


Figure 23. School-based interventions vs usual care: Exacerbations leading to hospitalisations

Subgroup analyses were not conducted, due to the lack of heterogeneity, and an increased chance that the studies would be underpowered. Sensitivity analyses could also not be conducted due to the small number of studies included in the models. All but one of the studies [95] reported on cluster RCTs, and half of the studies originally reported on binary outcomes [191, 229, 237], however no significant difference in effect size was seen. Egger's test for publication bias showed no evidence of publication bias (p = 0.626), although the small number of studies meant that the test was underpowered.

Two of the largest studies [95, 190] contributed three-fifths of the weighting to the pooled effect size, and had a low or unclear risk of bias across all the domains. In the study by Horner *et al* [190], a low risk of bias was seen for each domain, apart from the blinding of participants and personnel, which was unclear.

Primary Outcome Two: Exacerbations leading to ED visits

Effect sizes from 13 studies were included in the meta-analysis, and there was evidence that the interventions were effective in reducing the frequency of ED visits (OR 0.70, 95% CI 0.53 to 0.92; figure 24).

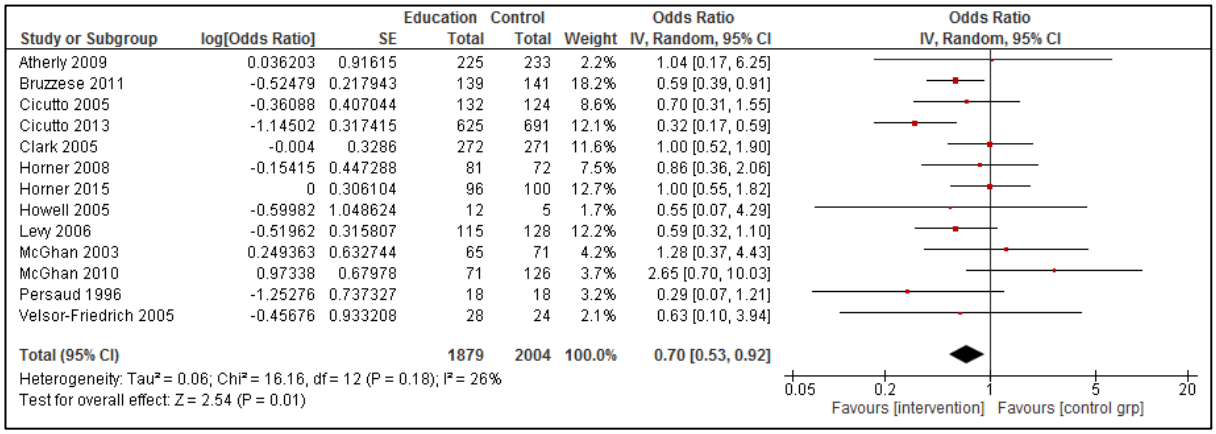


Figure 24. School-based interventions vs usual care: ED visits

Among these studies, there was substantial heterogeneity, both in the magnitude and direction of effect, with three studies have effect size close to one [190, 208, 229], and two studies suggesting a negative intervention effect [192, 195]. This resulted in an I^2 value of 26%.

The school type (figure 25), age, SES of the children and intervention deliverer involved in the intervention did not explain the observed heterogeneity seen. There was also no evidence that any

of the intervention conditions that consistently predicted successful implementation in the QCA analyses explained any of the heterogeneity seen.

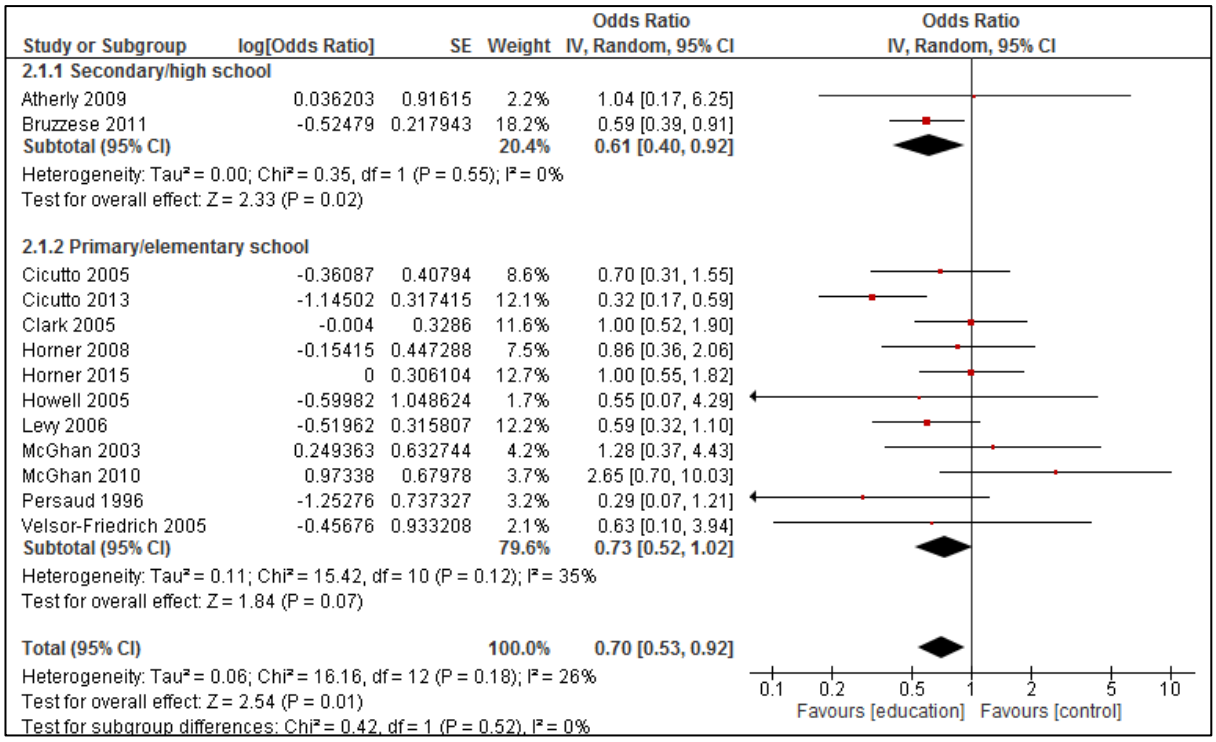


Figure 25. School-based interventions vs usual care sub-grouped by school type: ED visits

Due to difficulties in identifying levels of parental engagement, proxy analysis examined a simplified variable reflecting whether parents/carers were active participants, however this did not substantially explain the heterogeneity.

Studies that replicated one of the combinations that was found to trigger successful intervention implementation (five studies that were theory-driven, took place outside students' free time, and did not involve school nurses) had inconclusive effect sizes (OR 0.85, 95% CI 0.47 to 1.52), which differed significantly from studies that did not replicate a combination found to trigger successful implementation in the earlier QCA analyses (OR 0.67, 95% CI 0.47 to 0.94). Finally, subgroup analyses based on three of the conditions that were found to trigger successful implementation were conducted (theory-driven, took place outside students' free time, and parental engagement). All of the studies included in the meta-analyses had included at least one of these conditions, and subgroup analyses suggested that the number of components was inversely related to the effect size, with studies with one (OR 0.56, 95% CI 0.33 to 0.97) or two (OR 0.67, 95% CI 0.49 to 0.94) components having lower effect sizes than the three studies that included all three components (OR 1.48, 95% CI 0.65 to 3.40). However, the test for difference

between subgroups did not suggest that these were significant differences and there remained substantial heterogeneity within the subgroups.

Sensitivity analyses were conducted to explore the impact of decisions to transform or combine the data. No differences were detected in the effect sizes of studies that were originally measured through binary effect sizes (OR) and those originally measured through continuous measures (SMDs). No differences were detected by whether studies assessed intervention effects at 12 months, 4-7 months, or three months or less. All but two of the studies [95, 232] had randomised children at the school level, although there was little evidence that this distinction explained heterogeneity in effect sizes.

Supplementary analyses were conducted to assess the impact of study quality on effect sizes; categories of high and unclear risk of bias were combined. None of the included studies here had a high risk of bias for generation of a random sequence generation, although eight studies had an unclear risk. The results of the sensitivity analyses provided moderate evidence that studies that had a high or unclear risk of selection bias, with respect to breaches in allocation concealment, had significantly different effect sizes (OR 0.86, 95% CI 0.64 to 1.16), compared to the three studies that had a low risk of bias (OR 0.51, 95% CI 0.33 to 0.78). There was also evidence that studies with a low risk of bias for the collection of outcome data and the blinding of collectors were significantly more effective (OR 0.58, 95% CI 0.41 to 0.81) than the seven studies with an unclear or high risk of bias (OR 1.04, 95% CI 0.69 to 1.58). Differences in the risk of bias classification for other domains did not significantly explain heterogeneity in the effect sizes between studies.

Although based on a relatively small number of studies, Egger's test or the funnel plot indicated any evidence of publication bias.

Primary Outcome Three: School Absences

Ten studies were included in this meta-analysis, and there was no evidence that school-based self-management interventions were effective in reducing school absences (SMD -0.06, 95% CI -0.22 to 0.08; figure 26).

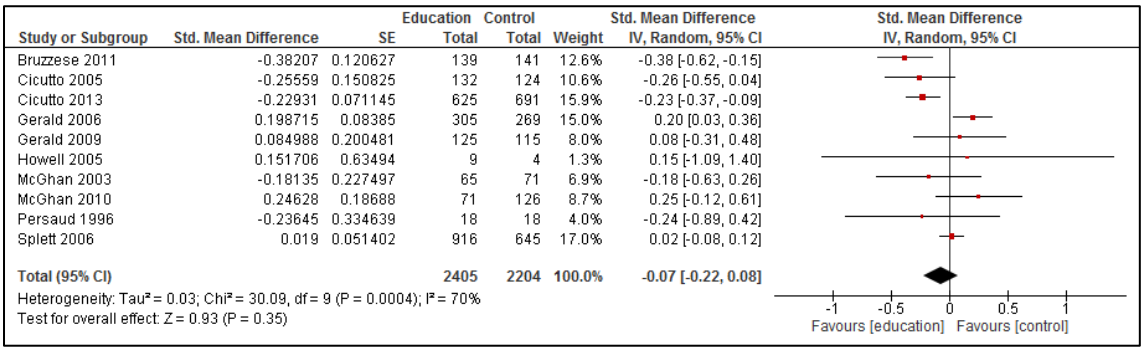


Figure 26. School-based interventions vs usual care: School absences

Among the studies, there was high heterogeneity between the effect size estimates, with an I^2 of 70%. Effect sizes from half of the included studies indicated that the intervention had a negative impact in increasing the number of school absences in the intervention group, relative to the control [192, 196, 212, 213, 238].

One study included in the meta-analysis focused on high schools [95], and was highly effective in reducing school absences (SMD -0.38, 95% CI -0.62 to -0.15); this study also seemed to drive much of the heterogeneity explained by subgroup analyses examining school type and children's age (figure 27).

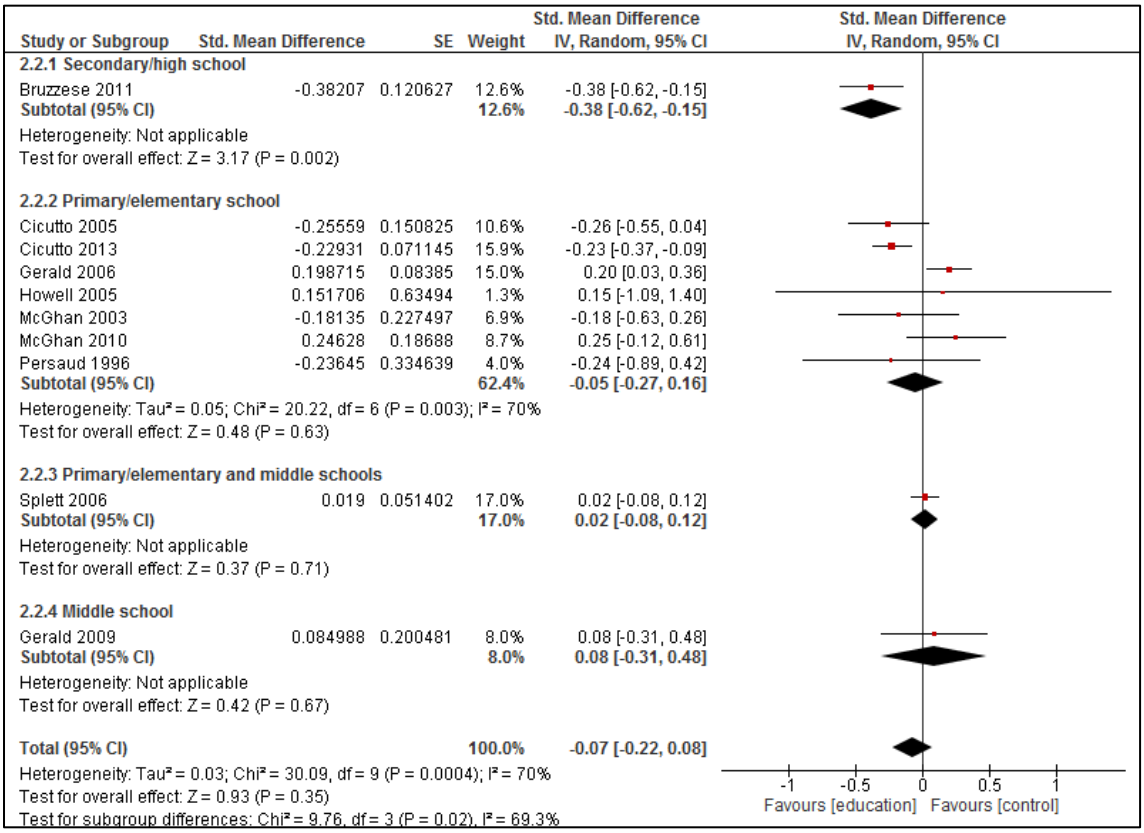


Figure 27. School-based interventions vs usual care sub-grouped by school type: School absences

Studies that included moderately high levels of children from lower socioeconomic backgrounds (between 25-50% of children) were significantly more effective in reducing levels of school absence (SMD -0.23, 95% CI -0.36 to -0.09) than studies with high levels of children from deprived backgrounds (over 50%), where the effect size was negligible (SMD 0.01, 95% CI -0.09 to 0.11) and studies where less than 25% of children were from deprived backgrounds, or where this was unclear (SMD -0.02, 95% CI -0.29 to 0.24).

Studies that included existing school staff in the delivery of the intervention were less effective (SMD 0.08, 95% CI -0.08 to 0.24) than studies that were mainly delivered and facilitated by external stakeholders (SMD -0.17, 95% CI -0.32 to -0.02; figure 28).

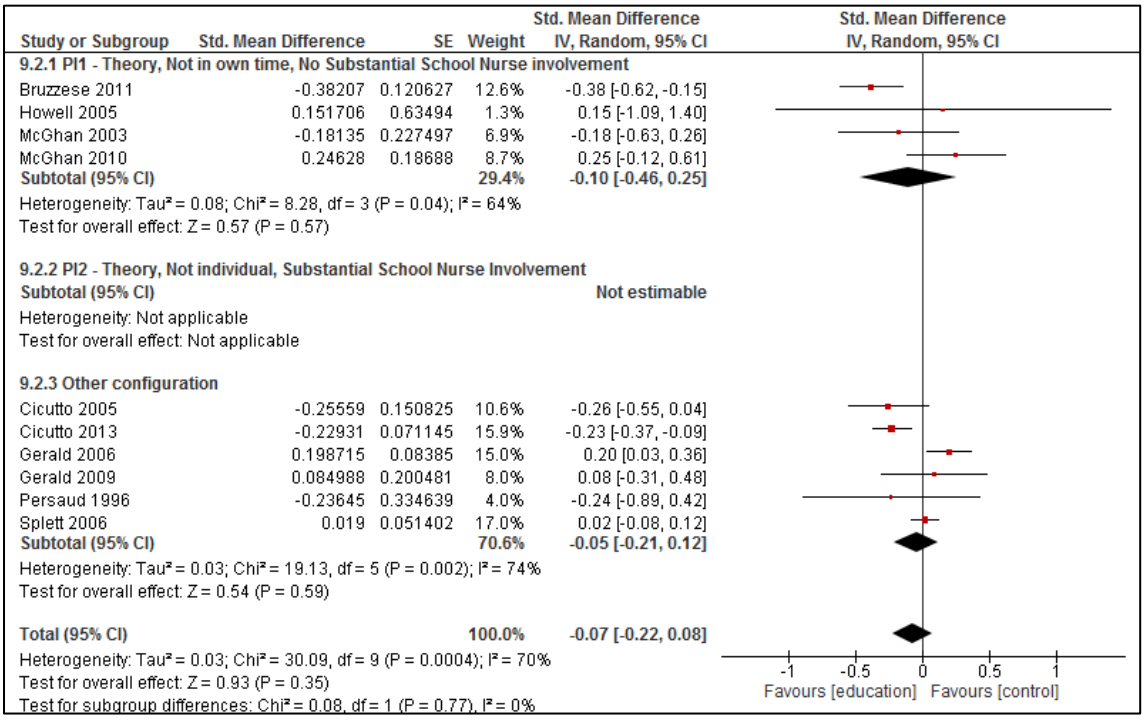


Figure 28. School-based interventions vs usual care sub-grouped by configuration of conditions: School absences

Subgroup analyses involving the conditions and combinations found to be sufficient to trigger successful implementation in earlier QCA analyses did not significantly explain the heterogeneity in effect sizes, with two exceptions. Interventions that took place during children's free time had greater impacts on school absences (SMD -0.23, 95% CI -0.36 to -0.11) than those that took place at another point in the school day (SMD -0.01, 95% CI -0.18 to 0.16), although a high level of heterogeneity remained among this latter group of studies (I^2 = 62%). Strong evidence was also seen around the role of theory, where studies that reported on a framework had a greater impact

on the pooled effect size (SMD -0.20, 95% CI -0.36 to -0.04) than those that did not (SMD 0.08, 95% CI -0.05 to 0.20), although some heterogeneity remained for studies that drew upon theory (I^2 = 41%) and those that did not (I^2 = 28%).

Sensitivity analyses showed no evidence that the transformations in effect sizes helped explain heterogeneity, and there was also no evidence that the unit of randomisation explained variation in effect sizes. The three studies that collected absence data within three months or less post-intervention, or where this was unclear [212, 213, 232] showed a weaker effect in reducing school absences, with two studies showing a negative effect [212, 213], although this was not significantly different from studies that assessed absences 12-months post-intervention. There was also no evidence that the risk of bias impacted the effect size. However, studies that had taken steps to blind the assessment of outcomes and avoid detection bias had a greater impact on school absences (SMD -0.27, 95% CI -0.38 to -0.17) than studies where steps had not been taken (SMD -0.07, 95% CI -0.02 to 0.16).

There was no evidence from the funnel plot of Egger's test that these data were impacted by publication bias.

Primary Outcome Four: Days of Restricted Activity

Three studies were included in the meta-analysis of days of restricted activity [95, 194, 197]. These provided evidence that the intervention mode could reduce the number of days of restricted activity experienced (SMD -0.30, 95% CI -0.41 to -0.18; figure 29), although the number of included studies is limited, and two studies evaluated the same intervention design. All three studies provided consistent evidence around the direction and magnitude of the effect.

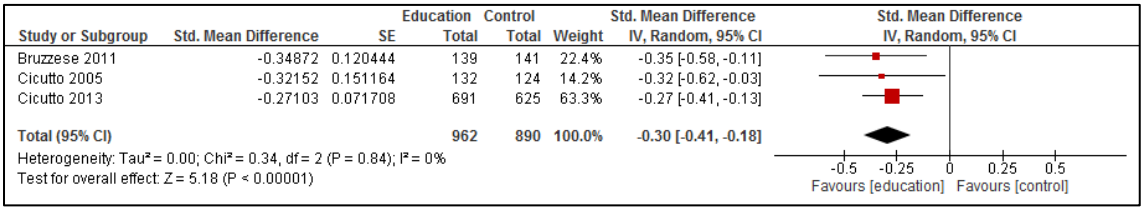


Figure 29. School-based interventions vs usual care: Days of restricted activity

Due to the low heterogeneity and the low number of studies, subgroup and sensitivity analyses were not reported. Notably, however, none of the included studies had a high risk of bias for any domain.

Secondary Outcome One: Unplanned Visits to a Medical Provider

Five studies were included in the meta-analysis here, and there was evidence that school-based self-management interventions did reduce the number of unplanned or unscheduled visits to a medical provider (OR 0.74, 95% CI 0.60 to 0.90; figure 30).

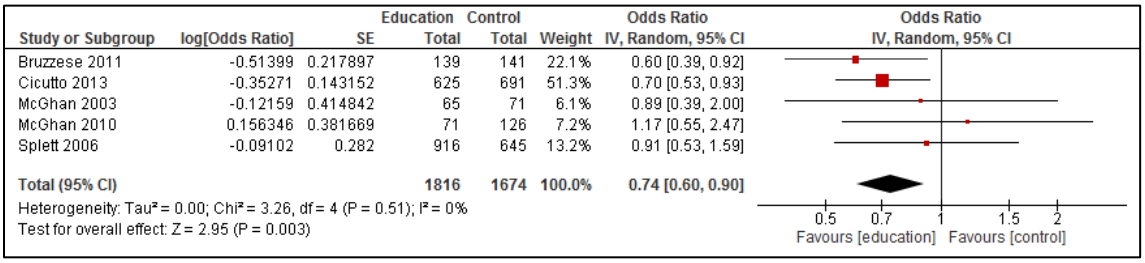


Figure 30. School-based interventions vs usual care: Unplanned visits to a medical provider

Despite some inconsistency in the magnitude of effect, there was little evidence of statistical heterogeneity. Due to the small number of studies, subgroup and sensitivity analyses were not meaningful. However, two studies contributed almost 75% towards the pooled effect size [95, 194] and neither study had a high risk of bias on any domain.

Secondary Outcome Two: Experience of day and night time symptoms

There was no evidence that school-based self-management interventions reduced the level of daytime symptoms that were experienced (SMD -0.15, 95% CI -0.32 to 0.02; figure 31), with the confidence interval just crossing the line of no effect.

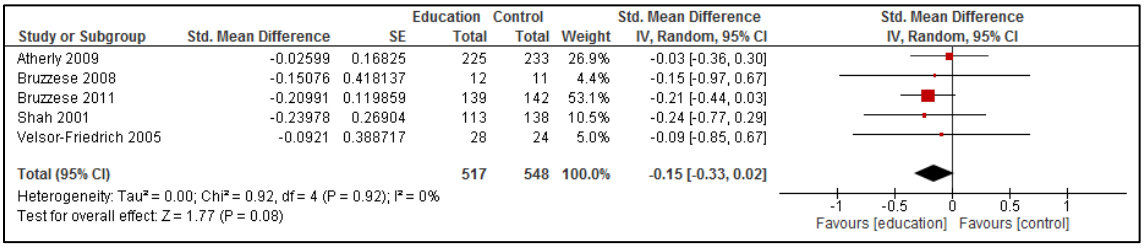


Figure 31. School-based interventions vs usual care: Experience of daytime symptoms

However, there was consistency in the direction of effects reported. There was even less evidence that school-based self-management interventions reduced the level of night-time symptoms that were experienced (SMD -0.18, 95% CI -0.51 to 0.16), with two studies providing weak evidence that night-time symptoms increased among children receiving the intervention. Sensitivity analyses found that night-time symptoms decreased (SMD -0.26, 95% CI -0.46 to -0.06), although due to the inconsistency in the direction of effect, the underlying assumptions of the fixed effects model cannot be validated.

Due to the low number of studies, subgroup and sensitivity analyses were not meaningful. However, one study that measured change in daytime symptoms [237] showed a weak effect that the intervention lowered the level of daytime symptoms.

Secondary Outcome Three: Lung Function

Outcomes measuring the impact on lung function were extracted from five studies, however these were not included in the meta-analyses due to conceptual and statistical heterogeneity.

Secondary Outcome Four: Use of Reliever Therapies (e.g. SABA)

Two studies were included in the meta-analysis here. The pooled OR provided uncertain evidence on the effect of school-based self-management intervention on the use of reliever therapies (OR 0.48, 95% CI 0.13 to 1.80; figure 32).

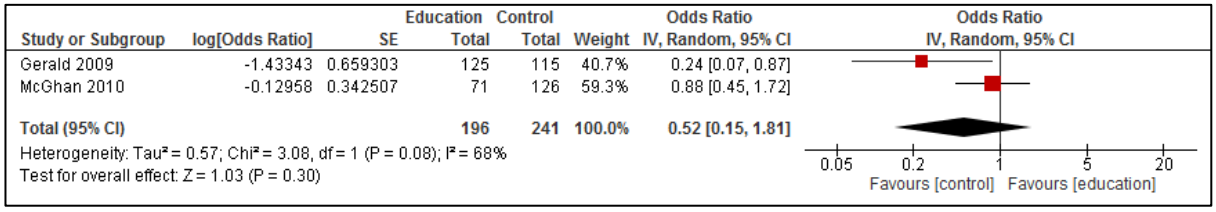


Figure 32. School-based interventions vs usual care: Use of reliever therapies

There was a high level of heterogeneity between the studies (I^2 = 74%), although both studies were consistent in the direction of effect indicating a lower odds of (frequent) reliever therapy use). One of the studies [238] had a low or unclear risk of bias across all the domains, while the other study [192] had a high risk of bias in terms of attrition and selective reporting.

Secondary Outcome Five: Corticosteroid Dosage (ICS usage)

Two sets of meta-analyses were initially constructed to reflect the studies that measured either usage, or appropriate use, or corticosteroids and add-on therapies. In the second model, two studies were included, although the direction of the findings differed and resulted in high levels of heterogeneity (I^2 = 87%) and therefore a pooled effect size was not estimated.

There was no evidence for the effect of school-based self-management interventions on children's use of corticosteroids and add-on therapies (OR 1.25, 95% CI 0.88 to 1.79; figure 33). There was no evidence of statistical heterogeneity between these studies, therefore reporting on subgroup analyses was not meaningful. One study in the model [95] had a low risk of bias on all domains except for the blinding of participants and personnel, where the risk was unclear. The two other

studies had a high risk of bias on one [195] and two domains [192], respectively; both studies had a high risk of attrition bias from incomplete and unexplained drop outs at outcome data collection.

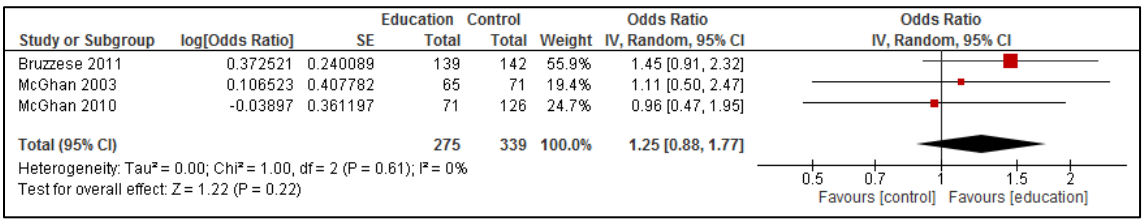


Figure 33. School-based interventions vs usual care: Corticosteroid dosage and use of add-on therapies

Secondary Outcome Six: Health-Related Quality of Life (HRQoL)

Due to conceptual differences in the way in which this outcome was measured, one meta-analysis of seven studies explored intervention impact on quality of life, measured through SMDs (figure 34), and provided evidence of effectiveness (SMD 0.27, 95% CI 0.18 to 0.36). This model showed no evidence of statistical heterogeneity in effectiveness, with all studies providing estimates of positive improvements, although these were not statistically significant in all studies.

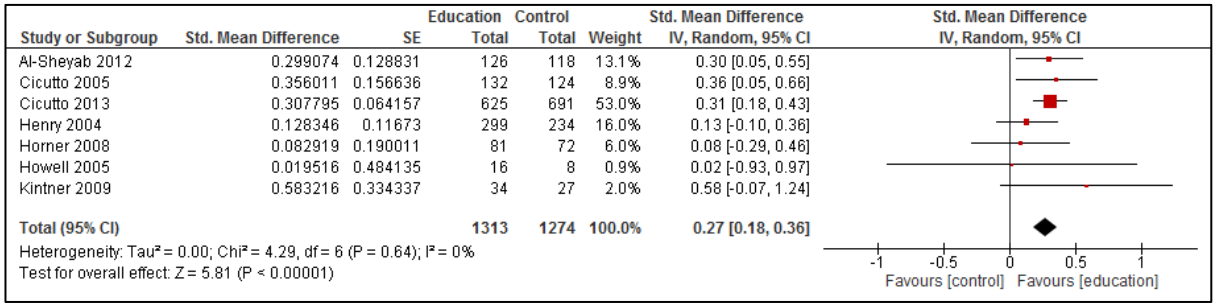


Figure 34. School-based interventions vs usual care: HRQoL

The low level of heterogeneity and low number of studies meant that subgroup analyses were not conducted. Five of the included studies [191, 207, 211, 212, 230] had a high risk of bias on at least one domain, although the two studies with a low or unclear risk of bias on all domains [194, 197] contributed over 60% of the weighted effect size. Explorations of publication bias were underpowered and could not be properly tested.

A second meta-analysis, including eight studies, also provided evidence that children in intervention groups had higher levels of health-related quality of life at follow-up than children in control groups (MD 0.35, 95% CI 0.06 to 0.64). The mean difference, while indicating that the impact did not cross the line of no effect, fell below 0.5 (the threshold indicating a clinically significant change in quality of life). There was high heterogeneity (I^2 = 81%) among the studies. One study [207] had high levels of baseline imbalance on this outcome, and sensitivity analyses

removing this value resulted in a lower point estimate, but much lower levels of heterogeneity (MD 0.21, 95% CI 0.07 to 0.32; $I^2 = 24\%$). Due to a low number of studies, further exploration of the heterogeneity was not explored, and an assessment of publication bias could not be conducted. Four of the included studies had a high risk of bias for at least one domain.

Secondary Outcome Seven: Study Withdrawal

There was no evidence that participation in the intervention was linked to study withdrawal (OR 1.14, 95% CI 0.92 to 1.42; figure 35).

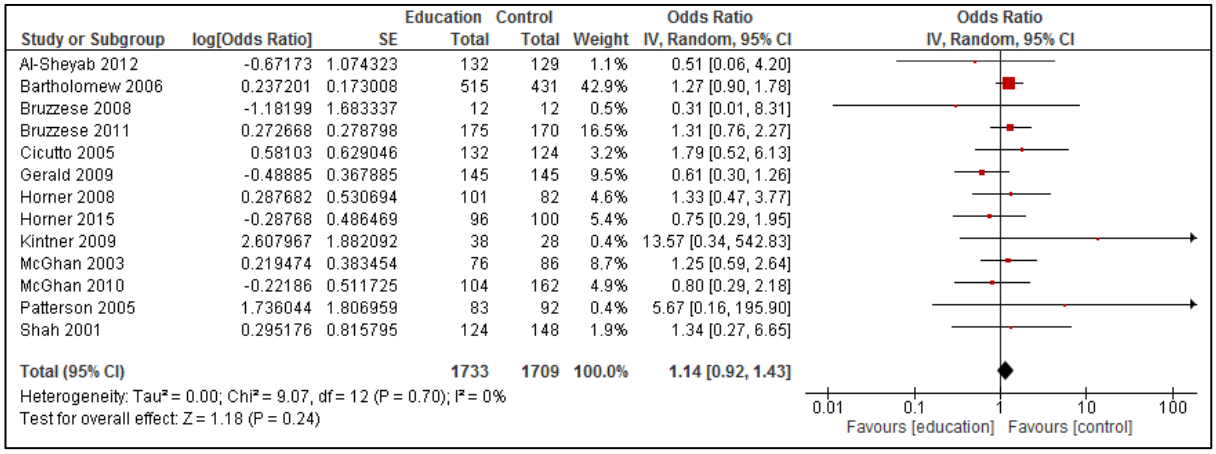


Figure 35. School-based interventions vs usual care: Study withdrawal

No substantial heterogeneity was seen, although there were some qualitative differences between studies that had low levels of withdrawal among treatment, relative to control groups [210], and those with very high levels [75, 230]; in neither case would the level of withdrawal be considered problematic (did not exceed 25% of participants) and the stark relative effect was driven by a small sample size in some studies [210, 230].

Despite the low level of heterogeneity, subgroup analyses were presented due to the link between withdrawal and the earlier stages of this review. When one set of combinations was replicated in the subgroup analyses to mirror the QCA findings, there was weak/uncertain evidence to suggest that studies that used theory, alongside running the intervention in students' free time and having no substantial school staff involvement, were less likely to have children drop out before the outcome assessment (OR 0.88, 95% CI 0.55 to 1.40) than studies with other combinations of conditions (OR 1.23, 95% CI 0.95 to 1.58). There was also no evidence that withdrawal from the study was associated with school type (figure 36).

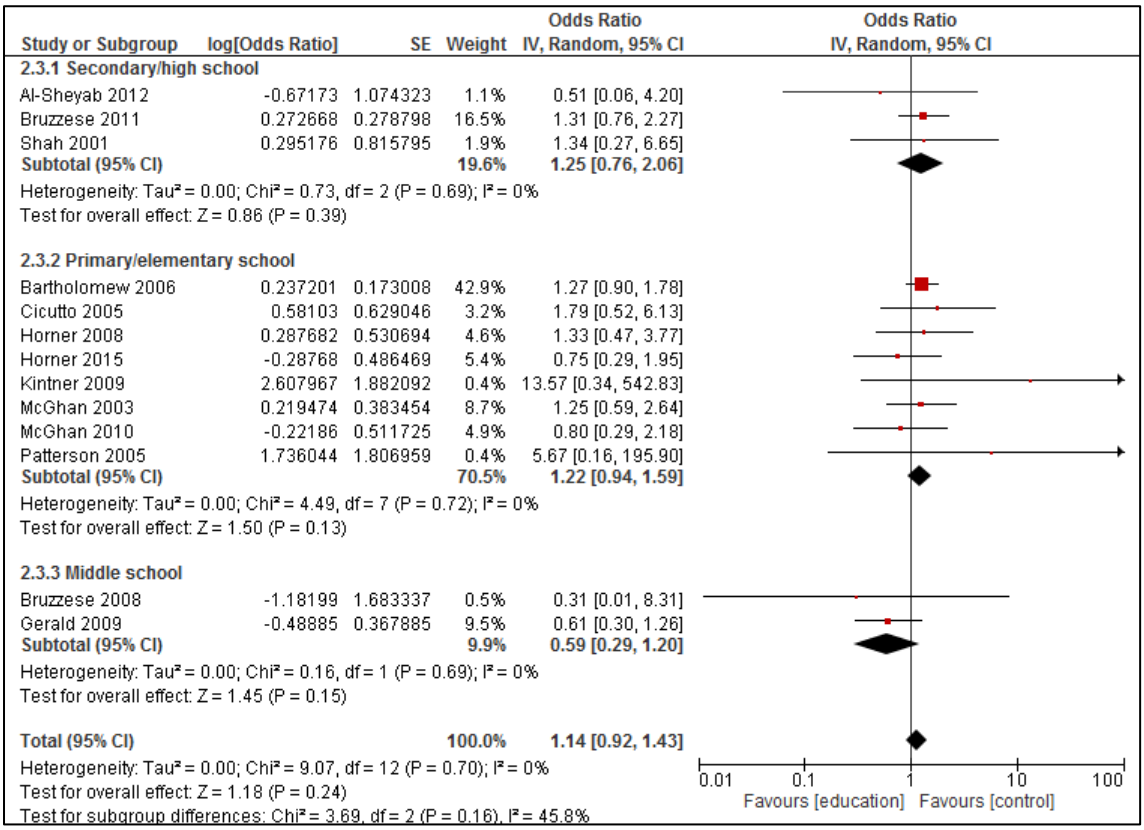


Figure 36. School-based interventions vs usual care sub-grouped by school type: Study withdrawal

Subgroup analyses aimed at understanding patterns of heterogeneity in the odds of withdrawal did not show that the timing of the assessment, the unit of randomisation, or the risk of bias explained patterns of withdrawal. This included risk of attrition bias assessments, although the meta-analysis explored differential patterns of attrition and did not account for instances where both intervention and control groups had high levels of attrition. There was no evidence that publication bias was a problem in terms of withdrawal.

5.4.5 Part Three: Adjunct Meta-Analyses

Adjunct meta-analyses were conducted to explore whether interventions that were successful in terms of implementation were also successful in terms of their effectiveness, using a subset of studies contained within the process evaluations. The studies here included a control group; however studies could have used a range of study designs, and control group children could have received an alternative intervention that may have included an asthma component.

Due to conceptual and methodological differences in study design, these studies only provide indicative evidence as to the impact of school-based self-management interventions on children's outcomes. Successful implementation was defined in the same way as the QCA analysis, and

represented a combined indicator around attrition, adherence and dosage. Two outcomes were considered – ED visits and school absences, where sufficient studies existed to form a meta-analysis. Both models included effect sizes from seven studies.

A meta-analysis of ED visits showed that the included interventions were successful in reducing the number of ED visits (figure 37), although with a high I^2 value of 52%, indicating high levels of heterogeneity.

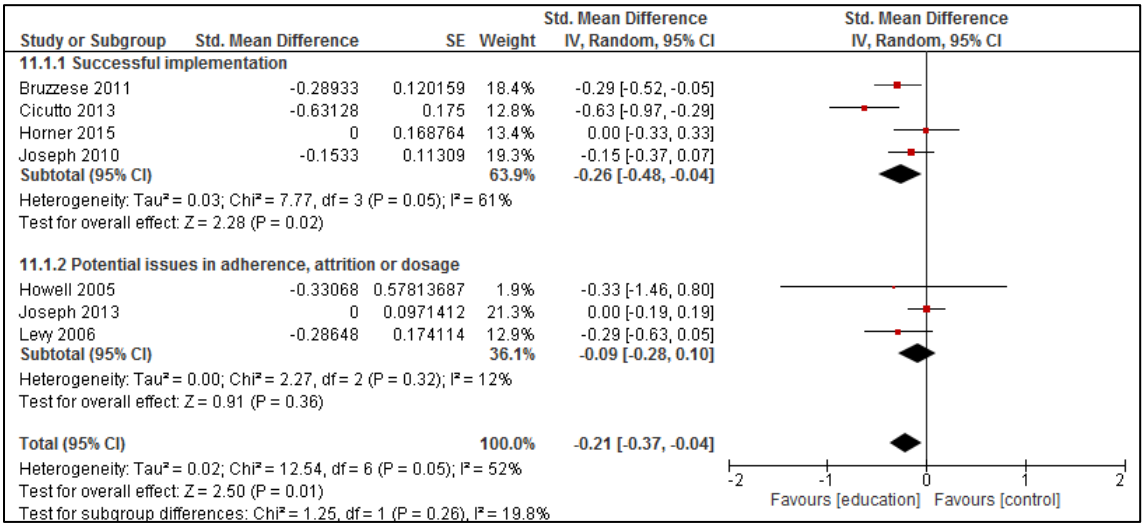


Figure 37. Adjunct analyses: Impact of implementation on ED visits

Subgroup analyses, based on implementation scores, showed that studies classified as being successfully implemented had a greater impact on ED visits (SMD -0.26, 95% CI -0.48 to -0.04) than those that were not as successful (SMD -0.09, 95% CI -0.28 to 0.10), although this difference was not significant (p = 0.26). A meta-analysis on the impact of school-based self-management interventions provided uncertain evidence that these interventions were successful in reducing school absences (SMD -0.12, 95% CI -028 to 0.04; figure 38).

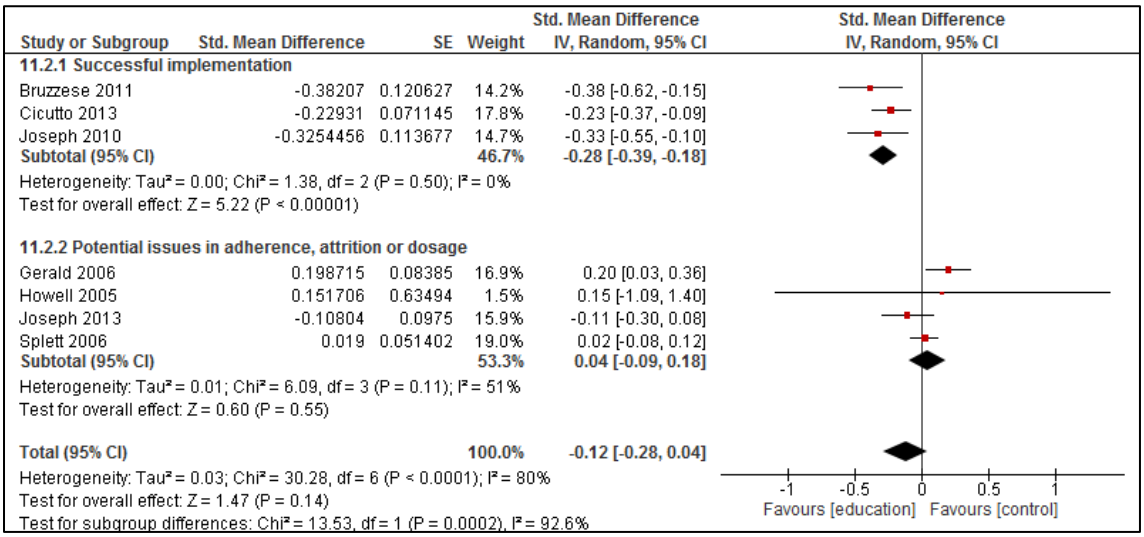


Figure 38. Adjunct analyses: Impact of implementation on school absences

However, subgroup analyses based on the combined implementation score indicated that studies that were successfully implemented had significantly higher effect sizes (SMD -0.28, 95% CI -0.39 to -0.18) than those that were not (SMD 0.04, 95% CI -0.09 to 0.18).

5.5 Discussion

5.5.1 Summary of the QCA Results

Having a named theoretical framework underpinning the intervention was one of the most consistently positive conditions that appeared in combinations of conditions that triggered a successful intervention. However, it is unclear whether a successful intervention could be attributed to a single theory; it is also unclear whether the theories that were used were suitable for the intervention, as it could not be ascertained how the theory was used to inform the intervention. Instead, the use of a named theory, in conjunction with other conditions, led to better implementation. The other conditions included running interventions outside of children's own time, reporting good levels of engagement from parents, and good satisfaction from children. The findings also showed that some combinations of conditions were specific to high schools only.

High levels of parental engagement was measured using high levels of cooperation in providing the information to trialists, as noted by the study authors [221, 222], cooperation with home or school visits [212, 216], attendance at seminars [210], or receiving telephone appointments from the trialists [216]. Conversely, some other studies reported difficulties with parental engagement,

particularly in obtaining consent or data collection [213, 224, 225], difficulties in participation [194, 214, 223, 226, 227], or in adherence or behaviour change [219]. Child satisfaction was also important in successful implementation; four studies showed that most children were satisfied with the intervention, based on qualitative statements based on stakeholder perceptions [207, 209, 212, 227]. None of the studies that were included in the QCA analyses reported low levels of child satisfaction, however one study that was not included in the QCA analyses delivered a low intensity intervention and reported low levels of satisfaction for some indicators [186].

The inclusion of school nurses in interventions also appeared to be important in achieving a successful intervention, where children were not engaged in personalised or tailored interventions. The timing of the intervention was also important, with interventions that were delivered outside of students' free time triggering successful implementation in two different combinations of conditions.

No single condition alone was sufficient for triggering a successful intervention, highlighting the complexity in achieving a successfully implemented intervention. This also highlights the use of the QCA approach in capturing complex pathways to achieving intervention implementation success. This is further indicated through the modest levels of coverage of any of the pathways reported.

5.5.2 Summary of the Meta-Analyses Results

The results from the meta-analyses showed that school-based self-management interventions can lead to small improvements in several outcomes, including hospitalisations, ED visits, and quality of life. A smaller number of studies suggested positive improvements in unplanned medical visits and days of restricted activity. The effects on school absences, experiences of asthma-related symptoms, and the use of medication were small, however the certainty for these outcomes was low or very low, and the confidence intervals included small or no effects. The strength of the evidence for the effectiveness of the intervention was stronger for urgent care contact and quality of life that it was for symptoms.

The most important intervention impacts were seen for outcomes involving healthcare use. These were measured in a number of ways, therefore several transformations of the data were required

to facilitate the meta-analyses. The magnitude of effect sizes for hospitalisations, ED visits and other instances of unplanned healthcare use were small across all three outcomes, when considered in absolute terms. However, it indicates that the intervention effect can reach to both primary and secondary care. Conversely, it was expected that a greater effect would be seen for school absences than the data showed. Heterogeneity was substantial in this outcome (70%), and subgroup analyses indicated that the way in which the intervention was implemented may impact on this.

The effects of the intervention were consistent across the outcomes, apart from school absences and ED visits. Although most of the investigations into heterogeneity was uninformative or inconclusive, there was an indication that school type and age could contribute towards explaining some of the heterogeneity seen for school absences, with the intervention having a greater impact on older children, although this was derived from a single study [95]. Two studies showed that interventions with moderate to high numbers of children from lower SES backgrounds [194, 195] resulted in fewer school absences for children in the intervention group, however the relationship between the proportion of children from lower SES backgrounds and the effect size was not linear.

5.5.3 Contribution of a Mixed-Methods Approach

The mixed-methods approach used in this review enabled further understanding of the design and implementation processes associated with more successful implementation of asthma interventions. This design also furthered the development of careful and theory-driven hypotheses for testing in meta-analyses, and explored the links between successful implementation and intervention outcomes. Adjunct analyses showed links between intervention implementation and more effective interventions. The meta-analyses were based on the QCA findings, and assessed the impact of school-based self-management interventions for asthma in improving outcomes, including school absence. This analysis also showed that individual conditions were often part of combinations that triggered successful intervention implementation, and explained some of the between-study heterogeneity. Notably, the studies that were theory-driven had a greater impact on reducing school absences than those that were not.

Further meta-analyses suggested that interventions that did not involve existing school staff in a substantial delivery or facilitating role were also those that achieved the greater levels of impact in lowering school absence. This echoes the QCA findings that involvement of school staff may not be effective under certain conditions. Interventions that are well implemented and are supported by theory can be implemented independently of school staff, appear to be sufficient for lowering levels of school absences.

5.5.4 Overall Completeness and Applicability

As mentioned above, most of the studies that were included in this review were conducted in the USA; very few studies came from either the UK or Europe. It is expected that additional factors relating to context (e.g. health policy and access to healthcare) are likely to influence the design and implementation of an intervention, however the impact of such factors was not analysed in this review. Nonetheless, while it is reasonable to expect that there would be little impact regarding the applicability of the intervention to a wide range of schools in middle and higher income settings, as the way in which children attend schools is fairly standard, the US focus of the studies may have implications in the transferability of the findings. The nature of access to healthcare, and the high number of people without suitable healthcare coverage, could mean that the intervention has a greater impact in US settings, particularly among those from low income populations, with high levels of under-diagnosis and restricted access to the correct medication plans. Several of the interventions were developed on this basis, and selected schools as the delivery site because education is universal, rather than on the basis of healthcare. It could mean that weaker effect sizes are seen in areas with better healthcare coverage, higher rates of diagnosis, and equal access to medication (e.g. the UK, where healthcare is free at the point of access).

Where there was stronger evidence of an intervention effect was commonly seen in those outcomes experienced by children with fairly severe asthma. For example, the study by Atherly *et al* [229] took place in high schools among children with mild to severe asthma. Around 3% of children had been hospitalised due to their asthma at baseline, and less than 10% had visited an ED. Unplanned visits to secondary healthcare is relatively rare in paediatric populations, as the findings later in this thesis will show. Further, while many of the studies examined the differences

between the intervention and control groups at baseline, it was unusual for the trials to assess whether the differences were according to whether children's asthma was well controlled, compared to poorly controlled, at baseline or at follow-up.

Many of the studies that were included were cluster-RCTs, however few of the studies reported on the effect of this clustering. School-level randomisation is important in terms of study feasibility, as well as in reducing the risk of contamination of treatment impact. However, the opportunity to explore this is not one that is commonly taken by researchers. This means that no comment can be made on the generalisability of the findings regarding different school cultures.

There was a better representation of high schools among studies included as process evaluations, than those included in the meta-analyses. This could reflect the difficulties of implementing RCTs in high schools compared with primary schools, however this was not addressed in the studies that were included in this review. Despite what the findings from the QCA showed, the meta-analyses showed little qualitative impact of conducting interventions in high schools, compared to other school types, although this is based on a low number of high schools included in subgroup analyses, and low heterogeneity for many of the healthcare use outcomes.

Many of the studies did not report on the outcomes that were specified in the review protocol, and further issues were encountered in the incompatibility of some of the reported effect sizes. The largest meta-analytic model included 13 studies, and all the models provided only a partial account of the activity. This means that some models could have been underpowered. The development of a core outcome set for future school-based asthma interventions may partially overcome this. Future systematic reviewers evaluating public health interventions may also wish to include a narrative analysis of all studies included on study design, which may examine the nature of the intervention, the types of outcomes collected, and the impact of the intervention on these outcomes [243], to achieve a more complete understanding of the impact and feasibility of the model.

Finally, since studies that delivered other asthma interventions were excluded, the value of running an intervention in school, compared with running an intervention in a hospital or community setting, is unknown. However, schools clearly provide access to large numbers of children with asthma in one place, including those who are considered 'hard-to-reach'. Therefore,

schools can be considered an important environment for delivering interventions that can improve both children's outcomes and overall healthcare use. The findings from the review have shown that school-based interventions for asthma are effective in improving several outcomes, and future interventions should consider a number of configurations, including instructor, theory, and timing, in the study design. The outcomes of this review will work in conjunction with the findings of this thesis (discussed in chapters four and five) to directly inform the development of a school-based self-management intervention for children with asthma in London secondary schools.

5.5.5 Quality of the Evidence

The summary of findings table references the quality of the evidence for the outcome evaluation studies, while the process evaluations were considered separately. While all the studies employed a robust randomised study design, there were problems with the implementation. A number of studies had a high or unclear risk of bias, although these did not seem to increase the effect size, and in most cases, did not systematically influence the direction of effect. Studies that had a low or medium risk of bias may have contributed to lower judgements around the quality of the evidence due to other factors, including the directness of the indicators. For example, school absences were measured in several ways, and not all approaches were specific to asthma-related school absences.

The quality of the evidence was moderate for two outcomes in the summary of findings table, pertaining to healthcare use, quality of life, and experience of daytime symptoms. Each of these outcomes showed positive intervention effects, however they were based on a moderate number of studies. For two further outcomes, the quality of the evidence was low (school absences and ED visits), and very low for medication use. The indirectness and the unexplained heterogeneity were the main reasons for this.

Further consideration should be taken when looking at the quality of the evidence that are not captured in the summary of findings table above. First, some cluster-RCTs which had a low number of clusters were not included in the analyses. These studies were comparatively small and therefore did not contribute significantly to the pooled effect sizes. The effect sizes were adjusted

to account for the impact of ICCs, and sensitivity analyses were conducted, however the possibility that the intervention effects are exaggerated, compared to individually randomised trials or large cluster-RCTs remains a risk. This risk should, however, be balanced against the potential bias introduced by overlooking information from smaller trials. Similarly, the effect sizes were consistent for most outcomes, with the most substantial transformations involving conversion between SMDs and ORs to develop a common metric. While this seemed to have little impact, and different effect sizes tended to be consistent in direction and impact, this is further evidence of the indirectness in the outcome measures, which suggests lower quality evidence. Conversely, the quality of the process evaluation studies was almost consistently poor, with most studies having a high or unclear risk of bias across several domains. This could be due to many reasons, but possibly highlights the lack of guidance around how to conduct a process evaluation, as well as the difficulties in identifying process evaluations in the literature. Just four studies were deemed to have a low risk of bias on most domains, of which only one study was considered a stand-alone evaluation [226]. The main weakness of the process evaluation studies that were included was that they lacked breadth and considered only a single process of importance in depth. A commonly occurring risk of bias among the included process evaluation studies was that the tools and methods of collecting and analysing the data were not always credible or reliable.

5.5.6 Potential Biases in the Review

This review has several limitations which need consideration. First, is the potential measurement error. There was variation in the way in which the number of outcomes were measured, for example lung function and school absences. There is no 'gold-standard' for measuring school absences, and a lack of continuity across the studies may reduce the validity of the findings. The data for both school absences and healthcare use may also be subject to substantial measurement error; for example, it cannot be said with certainty that all of the school absences and healthcare visits were due to asthma specifically, or were authorised by the school or medical centre. Measurement error may also be a factor with some of the covariates within the subgroup analyses. For example, SES can be measured in different ways (e.g. through household income, or evidence

of free school meals), and it was not possible to explore these differences in measurement within the scope of the review.

Second, is the effect size transformations. The review aimed to include as much trial data within the meta-analyses as possible, while maintaining construct validity across the effect sizes. This often required conducting data transformations to ensure the data were compatible. While attempts were made to ensure transparency in presenting disaggregated effect sizes alongside those that had been consolidated, there was potential for these analyses (and sensitivity analyses) to be confounded, and the underlying assumptions around the transformation of effect sizes may not hold with further investigation. While this is important to consider, it needs to be balanced against a loss of information from excluding studies that use different approaches to measure the outcomes.

Third was the potentially underpowered analyses and treatment of heterogeneity. A low number of studies were included in many of the meta-analysis models, and for random-effects models, the models may have been underpowered [244]. Heterogeneity was also encountered, and the low number of studies either meant that the subgroup analyses were unsuitable, or that the subgroups themselves contained a low number of studies.

Fourth was the identification of process evaluation studies. While guidance does exist on how to conduct process evaluations [177], this did not support the identification of process evaluation studies from a systematic review position. All of the process evaluation studies included an examination of the given process and implementation outcomes of interest, and their relationship with context; however, these spanned a range of studies. Although an inclusive strategy was developed around the identification of process evaluation studies, it is possible that some authors may not have considered their study as a process evaluation. Further, the guidance for process evaluations states that they can adopt a range of data collection methods, however many of the studies that were included did not use vigorous qualitative methods of data collection, which may have limited the understanding of some of the issues surrounding implementation.

Fifth was the issue of harmful effects. Some studies reported negative intervention impacts among children, such as increased levels of ED visits. Negative effects such as these may reflect the content of self-management information delivered to children, which may, for example, have

recommended greater contact with healthcare providers when experiencing asthma attacks. A narrative approach to the analysis of the outcome evaluation data may have led to a more nuanced understanding of why some interventions led to more negative outcomes among children.

Sixth was the issue of alternative explanations. Many other factors could have influenced the results of the review, which have not been considered. For example, although these are school-based asthma interventions, few of the studies considered the seasonality of asthma exacerbations and the relationship with the school year.

Finally, the low number of clusters was also a limitation in this review. Some of the cluster-RCTs that were included only had a small number of schools. While there is agreement that randomising one cluster per arm would conflate the randomisation/intervention and clustering effect, there is less guidance on the minimum number of clusters needed for a study to qualify as a cluster-RCT. Studies involving low numbers of clusters typically indicate a small trial, and often contribute only a small amount of data. Sensitivity analyses for studies with a low number of clusters per arm (2-3) were conducted to account for this. The results were generally inconclusive, and the inclusion/exclusion of these studies did not change the results of the meta-analyses, with the exception of one study [207], in one HRQoL model. These studies may be at risk of baseline imbalances, as well as further bias.

5.5.7 Implications for Practice

Asthma is a common condition in children that can hinder transition into adulthood, and place a huge financial burden on individuals and countries. The results of this review show that school-based asthma interventions are an effective way of easing this burden and reducing rates of unscheduled care. Over the course of a year, and among a group of 1000 children receiving the intervention with low baseline risks, the number expected the experience at least one ED visit due to asthma could be between 6 and 34 fewer, compared with children who do not receive the intervention. While the direction and magnitude of the results are generally positive, they should be taken in the context of the quality of the evidence, which was generally moderate for any outcome, and in the context of the high diversity of data encountered, which required a number

of transformations. The clinical significance of these reductions is also difficult to calculate, although quality of life improvements was not estimated to be clinically significant.

For health-policy makers, these findings highlight that schools may be an important location for delivering asthma self-management interventions to large numbers of children. Further, many of the included studies tested the intervention among financially deprived and marginalised children, who are often hard-to-reach. This suggests that the results may be generalizable to fairly diverse populations.

The results also indicate that delivering interventions outside of the clinical environment is effective, and this has implications for healthcare professionals and the type of relationship that they hold with the school and wider community, which follows recommendations from policy makers. Some of the interventions within this review did include fostering better links between schools and healthcare providers, however the majority involved trialists entering schools to deliver the intervention themselves. If this model were further developed, it may require healthcare professionals and/or teachers to deliver the intervention. School nursing in some schools may help this strategy; however, in settings where there is no school nurse present, this could be a challenge.

The mixed methods design in this review highlighted important features of interventions that are of interest to educational. The overall results suggest that gains in school absences are marginal, however a subset of theory driven interventions did achieve modest decreases in this outcome.

5.5.8 Implications for Research

There is evidence within this review that school-based interventions can help children to self-manage their asthma, and can result in fewer asthma attacks. The updated logic model in figure twenty-three summarises where the evidence has been found, and highlights where uncertainties remain. The positive results seen in healthcare use demonstrate that the intervention could be implemented in other settings with a limited degree of certainty that the intervention will achieve a small positive impact, and future reviews may have a larger evidence base to further establish this trend. However, heterogeneity was observed, in both the magnitude of effect sizes and the direction of effect, in studies collecting data on ED visits. Research conducted to specifically

understand how these interventions generated this effect would be useful for future trialists. For example, while baseline imbalances may contribute to this, further analyses may reveal the context and mechanisms that explain the effectiveness in other settings.

The review identified a heterogeneous group of process evaluation studies which were often of low quality and did not give a broad understanding of the processes undertaken and mechanisms of action which reflect the complexity of the intervention. Previous authors have noted the quality of the process evaluation literature [176], which is important for understanding the causal chains of actions occurring within public health interventions. This review also highlights that many researchers do not adequately assess the implementation and context of their interventions according to the MRC guidance on process evaluations, and few studies appeared in both sets of analysis conducted in this review. Further research to understand the barriers to preventing process evaluations being conducted is needed. A key outcome from this review is the need for the development of a tool or checklist that can be used to identify process evaluation studies during the searching and screening process.

One of the key differences in this review was that 33 studies were identified based on study design, but the largest meta-analysis models included just thirteen studies. The need for a more standardised approach to evaluating this model is clear. Models and principles for developing core outcome sets have been developed [245], however these have been primarily for clinical trial purposes. Some work has been conducted to consider which domains should be captured in paediatric asthma trials [246], however this review highlights that many studies continue to capture outcomes that have little value, both clinically and from a policy standpoint.

Finally, subgroup analyses suggested that intervention impacts were generally consistent across different types of school, for outcomes that supported subgroup analyses, and that school type did not explain heterogeneity. However, further studies are needed to fully understand the effect of school type on intervention impact, particularly in high schools. These findings should also be considered in light of the results from the process evaluation, which indicated that the distinction between school types was important for implementation.

5.5.9 Overall Conclusions

This review has shown that schools can be effective settings for self-management interventions that reduce healthcare use. However, the optimal setting for delivering self-management interventions has not been explored, and could be a direction for future research. Further, while the intervention aims and setting have been similar across all of the included studies, the interventions themselves differed substantially, and a further review may be needed to explore whether differences in outcomes are seen across different modes of asthma intervention. This could include exploring the effectiveness of different programmes (e.g. Open Airways for Schools). Further research may also establish a better understanding of the links between intervention inputs and more distal outcomes, which may be more important for public health decision-makers. The feasibility of this research is dependent on a more mature evidence base emerging for this type of intervention, both in terms of the number of studies available, as well as improvements in the collection of standardised outcomes and reporting of processes undertaken and implemented.

Plain Language Summary

Asthma is common in children and young people. Improving children's ability to self-manage asthma is important in reducing the harmful effects of asthma. Schools are a potential site for developing self-management skills, but the evidence that school-based interventions improve asthma control has not been reviewed in a systematic way.

The aim was to review school-based self-management interventions for children with asthma. The systematic review addressed two questions: (i) what parts of an intervention are more likely to make it successful, and (ii) what effect do interventions have on children's asthma control, their school attendance, and their attendance at GP and hospital settings.

A total of 66 studies were included; 33 studies were included to understand the best way to deliver an asthma intervention, and 33 different studies were included to understand whether the interventions were successful in improving children's health and well-being.

Twenty-four studies were included in quantitative models measuring outcomes. School-based self-management interventions improved outcomes including hospitalisations, emergency department visits and health-related quality of life. Fewer studies improved unplanned medical visits and days of restricted activity. The interventions were not effective in reducing school absences, experience of day and night time symptoms, and medication use. Including parents in the intervention, and making sure the children were happy with the intervention, were also important in delivering interventions within schools.

The quality of the evidence varied across the studies. The studies measures whether an intervention had a strong study design, but there were some issues in the way that some had been delivered and the outcomes had not been measured accurately in all studies. The studies that were included to understand how to deliver an intervention could sometimes be biased, therefore the quality of the evidence was generally lower for these studies.

Chapter Six: Overall Discussion and Future Research

6.1 Overall Messages

In this thesis I have generated novel data on current levels of asthma control and medication adherence among children and young people with asthma in London secondary schools. The potential for these data to inform effective school-based interventions is supported by the findings supported by my Cochrane systematic review of school-based self-management interventions, using a mixed-methods approach to analysis, which provides the first robust evidence that school-based interventions can successfully improve some outcomes in children. These improvements are, albeit, mainly relating to healthcare use, since there was no evidence was seen for outcomes such as school absences and day and night time symptoms. Furthermore, data from the process evaluation in the Cochrane review suggest that the best interventions are ones that adopt a theory-driven approach.

A key finding from data from the online questionnaire is that despite suboptimal asthma control, by the validated ACT, in just under half of asthmatic children surveyed, many of these students with poor control believed that their asthma was well controlled – a finding that was accompanied by a high prevalence of poor adherence (irrespective of level of asthma control). This finding already has had impact with reports in the London press (https://www.standard.co.uk/news/health/toxic-air-warnings-must-include-reminder-for-children-to-use-inhalers-a3500881.html, accessed 21/6/18). Other key findings include high levels of unplanned medical attention and school absences, particularly among those with poorly controlled asthma, according to the ACT, and gaps in knowledge regarding the ICS $\pm$ LABA inhaler, and the spacer, with many students being unaware of the role of these in their treatment plan.

I was able to add further 'depth' to questionnaire data by running a series of focus groups, which further elucidated some of the barriers to adherence among teenagers with asthma in London. These focus group data strongly suggested that there were several practical and social barriers to medication adherence in teenagers. One putative and unexpected barrier to overall good self-management was a lack of awareness, both among themselves and among peers. Thus, the question remains is how I can use these novel data to improve asthma outcomes in London children. One way is to directly address key knowledge gaps and damaging perceptions in schools in order to improve control. In this final chapter, I therefore describe the potential for my findings to inform such an intervention – the feasibility of which is currently being evaluated in a grant funded study.

6.2 Future Research - Proposed Intervention

Three major themes that need to be addressed in a school-based intervention emerge from my data:

i. A better understanding of the current levels of asthma control in secondary schools in London

ii. Improved understanding of the barriers to medication adherence and asthma self-management among secondary school students

iii. A requirement for a school-based self-management intervention, to be piloted in London secondary schools.

The key unmet needs that will be addressed in a pilot school-based self-management intervention cover those that emerged during the focus group component of this thesis. This includes peer awareness, knowledge about asthma medications, GP communication, and general asthma management. Challenging incorrect beliefs are important during childhood and adolescence, particularly as young people prepare for the transition to adult care. The effects of poor self-management and non-adherence can also last into adulthood, if they are not addressed early.

Using my data, and working with my supervisor Professor Grigg, I devised a preliminary theory-based multifaceted intervention, in accordance with the Medical Research Council (MRC) framework for complex interventions [247]. The aim of this intervention is to improve asthma control, through improved self-management behaviours, in young people. The PRECEDE-PROCEED model was used to conduct the initial social epidemiological, educational and administrative diagnoses. This model works backwards from the desired outcomes of an intervention to identify the most appropriate strategies for achieving the objectives. The behaviour change wheel [248] was subsequently used as a framework to translate the key behaviours into the intervention using behaviour change techniques.

The intervention aims engage both teenagers with asthma and their peers, and it will be delivered in three components:

i. A theatre workshop for all year seven and eight students. The aim of this component is to raise awareness of asthma in schools among peers;

ii. A series of four self-management workshops for children with asthma only. The aim of this is to teach children with asthma about the disease, using interactive elements, including games and role plays.

iii. The children will be followed-up for 12 months after the intervention

6.2.1 Intervention Framework

Intervention Objectives

The intervention includes one primary objective: To test the effectiveness of an intervention to improve asthma control in adolescents with asthma, through a targeted school-based self-management intervention. The secondary objective is to raise awareness of asthma in schools among peers. This will be addressed through the delivery of a theatre workshop (not developed as part of this thesis), in collaboration with Greenwich and Lewisham Young People's Theatre (GLYPT) Company.

Study Design

The intervention will be a cluster-randomised trial, with schools acting as the unit of allocation. There will be three intervention arms:

i. Asthma workshop and theatre group

This group will receive the theatre performance, to be delivered to all children in years seven and eight. This group will also receive the self-management workshops for all children with asthma in years seven and eight.

ii. Theatre only group

This group will receive the theatre performance only. This was included as a treatment arm as peer awareness was an important barrier to adherence, as identified in my earlier focus groups. This arm will identify whether raising peer awareness in schools is sufficient to change self-management behaviours among children with asthma, without the self-management workshops.

iii. Control group

This group will receive usual care for the duration of the intervention. The control schools will receive the intervention at the end of the study when all the data has been collected.

The intervention will take place in secondary schools. The theatre performance will be delivered to the children first, and this will take approximately two hours. At the end of the performance, the main character will stay in role, and the children in the audience will have a discussion with her about her behaviours, including why she hides her asthma from her friends. The self-management workshops will be delivered a maximum of two-weeks later, and will take place over one school day. Baseline data will be collected, followed by 3, 6 and 12 month follow-up post-intervention. All data will be collected using an online questionnaire, which will be based on the questionnaire used in this thesis, with added scales on beliefs about medicines, knowledge of asthma (rather than medication only), and attitudes towards asthma.

In line with the methods discussed in this thesis, opt-out consent will be obtained for this study. For the children without asthma, consent to participate in the theatre workshop will be provided by the school as part of a learning tool. It is anticipated that the results of this pilot feasibility study will inform the development of a larger trial, to be delivered in secondary schools nationwide. Figure 39 shows a figure of the planned intervention.

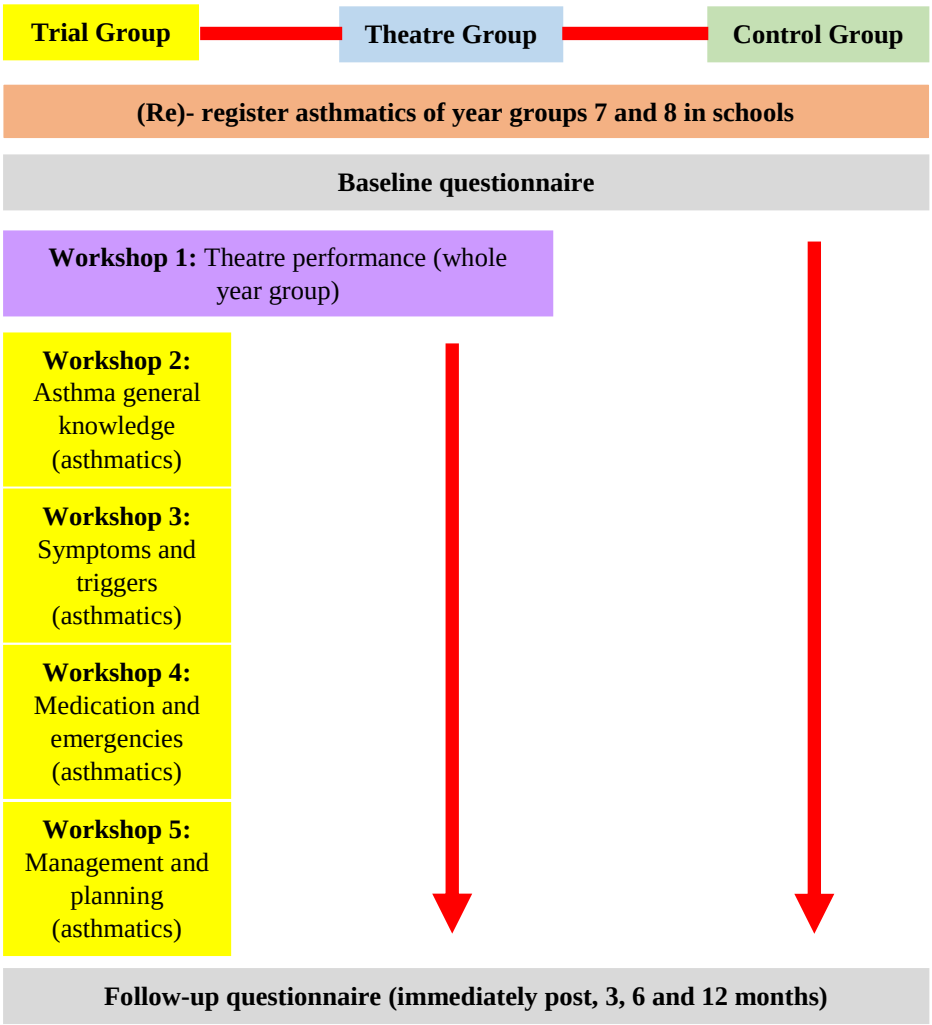


Figure 39. Planned intervention

Recruitment

The target population for this study is children with asthma in years seven and eight, who are attending secondary school in London. Recruitment will use the same strategy as the recruitment process discussed in this thesis. Maintaining allocation concealment, the schools will be randomised to one of the three intervention arms. As per my PhD research, the schools will be responsible for disseminating the information sheets and withdrawal forms to parents.

Methodology

The primary outcome will be asthma control, which will be measured using the ACT. The secondary outcomes will be medication adherence, which will be measured using the Medication Adherence Rating Scale [249]; unscheduled care, which will be measured using the questionnaire from this thesis (found in appendix three); asthma attitudes, which will be measured using the Brief Illness Perception Questionnaire [250]; school absences, which will be measured using the questionnaire from this thesis; asthma knowledge, which will be measured using a scale adapted from an earlier study about asthma [251]; and beliefs about asthma medication, which will be measured using the Beliefs about Medicine Questionnaire [252].

As part of the theatre workshops, a play about asthma will be delivered to all students in years seven and eight, to facilitate awareness and understanding of asthma among the direct peer group. At the end of the theatre workshop, the main character will stay in role to encourage audience participation and discussion. As identified in the focus groups (discussed in chapter four), peer awareness was a key barrier to adherence among teenagers in schools. Through changing attitudes and awareness among peers, it is expected that students with asthma should feel less concerned about the social barriers that currently prevent positive self-management behaviours.

Following the play, four self-management workshops will be delivered to children with asthma. Each workshop will last approximately one hour, and will include a series of games, role play, short films, and discussions. The main topics will include asthma general knowledge and understanding, GP communication, asthma triggers and symptoms, medication and emergency response, and self-management techniques and goal setting. The schools will also receive a toolkit, including emergency response posters, and advice on asthma friendly schools.

Statistical Analysis and Study Power

Adjusting for a 15% attrition rate, a minimum of 360 children will be required for this study, from 18 schools (six schools in each intervention arm; 20 students with asthma from each school). This sample size was calculated using my ACT score data (described in chapter three) as the primary outcome measure. This calculation is based on 80% power and a significance level of 5%, to test a 3-point difference in ACT scores. This was chosen as this is the minimal important difference. The standard deviation (SD = 4.3) that was used in the power calculation comes from the questionnaire data discussed in chapter three. The ACT was chosen to assess the outcome measure as this is a continuous outcome and is therefore more sensitive to differences in asthma control.

The power calculation is adjusted to allow for Intracluster correlation (ICC), as is required for cluster randomised trials. An ICC of 0.07 was chosen, taken from a study of asthmatics where a questionnaire was the outcome measure, but the clusters were randomised to GP surgeries, rather than schools. This means that the ICC is likely to be a conservative estimate for this intervention, as children in different schools are likely to be less heterogeneous than patients in different GP surgeries. A fully copy of the protocol can be found in appendix 13 and is registered on the ClinicalTrials.gov database (reference MGU0400).

6.3 Summary of Thesis Findings

The findings from this study show concerning levels of asthma control, knowledge of asthma, and medication adherence among children and young people in London secondary schools. The findings from the focus groups also highlighted some of the barriers to medication adherence, including social concerns and incorrect medication beliefs. The levels of poorly controlled children with asthma seen in this thesis may contribute, at least in part, to furthering understanding of the reasons for excess paediatric deaths from asthma in the UK, compared with other European countries. The findings from the systematic review also showed that school-based self-management interventions can be effective in improving outcomes, particularly rates of unscheduled care and quality of life, however consideration must be given to the study design, in accordance with the outcomes of the process evaluation analysis.

The findings from this thesis highlight the impact of poorly controlled asthma on quality of life, and the data from the questionnaire showed that the children with poorly controlled asthma, according to the ACT, had higher incidences of unplanned healthcare use and school absences. This mirrors existing findings, for example, Chapman *et al* [44] found that, in a sample of 10428 people with doctor-diagnosed asthma in

Toronto, 59% of those with uncontrolled asthma required at least one urgent care, or specialist visit, compared with 26% of those with well controlled asthma, and 15% of those with completely controlled asthma. The GINA guidelines ascertain that, in achieving good asthma control, rates of unscheduled care should reduce, therefore reducing the financial burden currently based on global healthcare systems. There is evidence from this thesis, given the findings of the systematic review, that school-based interventions may also contribute to a reduction in healthcare use, which may also ease the financial burden currently placed on healthcare systems.

The National Review of Asthma Deaths, published in 2014 [14], found that incorrect beliefs about the risk of an adverse outcome was seen in children and young people who suffered a preventable death from asthma. This has also been shown in the Room to Breathe Survey [74], where parents also demonstrated highly optimistic views of their child's asthma control, which could translate to the opinions of the children as they progress into adolescence. The children in the focus groups also revealed high thresholds when defining asthma control. Improvements in perceived asthma control, to correspond more closely with actual levels of control, have been associated with a reduction in asthma symptoms and other clinical markers of asthma control [253], and could be a step towards improving asthma self-management behaviours.

Considering medication use, 2.3% of the students (n = 18) in this study were prescribed a SABA inhaler only, and scored the maximum of 25 on the ACT, concurrent with no asthma symptoms. This indicates that some students may have outgrown their asthma, or may have been incorrectly diagnosed, and suggests that, although small, there is evidence that some children with asthma are over-treated, and potentially need a step-down approach to treatment. Similarly, 9.8% of the children in this sample (n = 75) scored 19 or less on the ACT, indicative of suboptimal control; however these children also self-reported having a SABA inhaler only, and may therefore need to step-up their treatment. However, these conclusions are based on responses to the ACT only and would require further investigation by a doctor. Evidence of over and under treatment for asthma has also been reported in Denmark; one study found that 50% of people had been incorrectly diagnosed [254]. The absence of a gold-standard diagnostic test for asthma may be a possible explanation for over-treating asthma, and inhalers can be prescribed based on the presence of symptoms alone, without further testing for airway inflammation [34]. Under-treatment of asthma may originate from a historical reluctance from doctors to diagnose asthma too quickly, and provoking anxiety in parents and children.

Medication adherence was also concerning, with over half of the sample self-reporting that they do not always adhere with their treatment plans. Although it cannot be determined whether poor asthma control is related to inadequately prescribed treatment, or poor adherence to treatment plans, non-adherence in this sample was higher among students with poorly controlled asthma, despite knowledge of asthma medications being higher in this group. This suggests that poor adherence to medication may be contributing to the levels of control. The qualitative data found that non-adherence with asthma medication is more intentional than the questionnaire data indicated. Although not directly measured in this thesis, it could be that incorrect attitudes and beliefs towards medication are a contributing factor to adherent behaviours.

6.3.1 Successes and Limitations

This thesis is the first the UK to assess asthma control using the ACT in London secondary schools. One of the key successes of this study is the large dataset that was obtained (n = 766), and the broad geographical location of participating schools. However, data from the Governmental Department for Education indicates that there are approximately 495,665 students attending secondary school in London [148, 255]; according to Asthma UK, there are an average of three children in every school classroom with a diagnosis of asthma [6]. Therefore, there are an estimated 49,566 students in London secondary schools with asthma, based on an average class of 30 students [256]. Accordingly, the final sample of 766 children is representative of just 1.5% of all secondary school students with asthma in London, therefore the generalisability of the findings is limited.

A second key strength of this study is the collection of data within the school environment. The school is an important location to consider for future research as it provides access to large numbers of children with asthma in one location, regarding of ethnicity, SES, or asthma severity. This includes children who do not regularly attend medical appointments. Collecting data in schools also reduces potential bias from parents/carers and/or clinicians regarding responses to questions. It is important that parental input was not included in the data collection, as children spend a large proportion of their day at school, away from their parents/carers.

A third strength of this thesis is the qualitative data that was collected through the free-text part of the questionnaire, and subsequent focus groups. This provides greater insight into the attitudes and beliefs of

young people, which cannot be achieved through quantitative data alone. However, the 'light-touch' approach to the analysis of the qualitative data, as discussed in chapter four of this thesis, may arguably reduce the validity of the conclusions that were reached.

Despite the notable successes of this thesis, there are also several limitations that should be considered. First, the data that was collected was self-reported, therefore the reliability of the findings may be reduced. The prescribed medication data was collected from the students, however it was not validated with clinical reports. Therefore, it is unclear whether the students were accurate in their reporting. For example, one student self-reported being on an unopposed LABA. This could be their genuine medication, however it is unlikely as it would not be recommended by a clinician; therefore may also indicate that some of the children could be unable to accurately recall their medication, despite being supported by photographs and a google search. Some students also self-reported that they had an ICS + LABA inhaler, however selected the option in the questions about this medicine that stated that they did not take this medication. This discrepancy in responses accounted for 5.7% of the total responses from children who reported using a preventer inhaler, however it is still an important consideration in the context of the findings.

The self-reported data regarding prescribed medication was not validated by clinical records, as the questionnaire responses were anonymous, in line with the ethical considerations outlined in chapter three. Data was also not obtained regarding the prescribed dose of ICS medicine, nor the clinical justification for the dose. Therefore, it is unclear from the findings whether or not poorly controlled asthma is due to an inadequate medication prescription, poor adherence with the prescribed medication, or a combination of both of these factors.

The self-reported data also raises questions about the reliability of the asthma control scores, as asthma control was measured using the ACT alone. Some of the students who scored 20 or above on the ACT, indicative of good asthma control, still self-reported days off school and instances of unplanned medical attention. It would be expected that children with well controlled asthma, according to the ACT, would not experience school absences due to their asthma, or unplanned medical visits. While this could be due to incorrect reporting from the students, it also raises questions about the reliability of the ACT measure. The ACT is not a perfect measure of asthma control, however it was chosen for this study as it was clinically validated in the target age group, and it can be completed by the children away from the clinical environment. It also covers a wider range of aspects related to asthma, with a scoring scale, therefore the

ACT provides a more detailed overview of a person's asthma control. However, the ACT is limited in that the scores towards the cut-off point of 19 are subjective, and the clinical difference between a score of 19 and a score of 20 is small, and the ACT does not consider differences in reporting between different people around this score point. A limitation of this study is that the ACT scores were not supported by spirometry, to give a better indication of clinical state.

The self-report nature of the data also limits the reliability of the findings, as it remains possible that some students were not honest with their responses, therefore increasing risk of social desirability bias. Some students could have answered the questions, based on how they wished to be perceived, rather than based on true experience. Although this risk was reduced where possible by ensuring that all responses were anonymous, and could not be linked back to them, due to the layout of some classrooms, it is possible that the students could see each other's computer screens, which may have influenced the data that was reported.

The recruitment process also served as a key limitation to this thesis, particularly the generalisability of the findings. An opportunistic sampling method was used for recruitment, and schools were only included if they were interested. All of the secondary schools in London were contacted and were invited to participate, however only 24 schools accepted the invitation. This yielded a very low response rate, and represented 4% of all the eligible schools in London. Therefore, the results may therefore not be generalizable to the wider London secondary school population. The individual asthma policies for each school were also not considered, nor was any history of the school participating in any other research separate to this one.

There was also a low response rate from the students within the participating schools. The total sample size represented 57.2% of all eligible students across all the schools. Therefore, the findings in this thesis are only reflective of just over half of the student body across all the participating schools. The proportion of children with poor asthma control, or with unplanned medical visits, for example, would likely be very different if the response rate across the participating schools had been closer to 100%. Among the students who did participate, there was a 40% non-response bias, which also significantly reduces the representation of the findings. Similarly, the generalisability of the findings is also limited due to the increased proportion of black and ethnic minority students in the sample, compared with the London population [257]. However, the ethnic diversity in the current sample does reflect the ethnic variation in some areas of London, particularly in East London boroughs, where a large proportion of the schools were recruited from.

The ethical approval obtained by the REC stipulated that students were only eligible if they had doctor-diagnosed asthma, and were identified by the school. Therefore, no screening process was imposed for children before their participation. Students were identified either by an official school register, or by school staff. Therefore, it is likely that some eligible children were not invited to participate, due to inaccurate reporting by the schools. This study did highlight a problem with the recording of asthmatics in the participating secondary schools, with many schools reporting far fewer asthmatics than would be expected. Currently, no data exists on the prevalence of children with asthma in London secondary schools, however data from Scotland indicates that the prevalence of asthma in Scottish primary schools is 14% of the student body [74]. The current data found that the lowest asthma prevalence in the schools was 4.6% of the student body, and one school reported just 12 asthmatics out of 1256 enrolled students. On speaking with the teachers about their methods of recording health data for the students, it is understood that medical information is collected when the students join the school, however it is not clear whether these records are updated regularly. This highlights a need for a more comprehensive registration of asthmatic children in London schools. However, it may also be that some children and/or their parents are reluctant to identify as asthmatic.

Despite some major limitations, the research reported in this thesis clearly showed that an online questionnaire is a highly effective way of obtaining data on asthma from large numbers of children in secondary schools. When combined with parental opt/out consent, and student assent, I argue that this method of data collection is a useful way of accessing large numbers of children to generate large amounts of data in a cost-effective way. An estimation of the costings has shown that the intervention will cost approximately £458,000 (including researcher costs and hosting the intervention), amounting to approximately £420 per child. Combined with the findings from the systematic review, the school environment can be considered an important third space for delivering interventions aimed at improving outcomes for children with asthma. Despite the limitations regarding the representativeness of the data, the findings highlight a concern regarding asthma control and medication adherence in London secondary schools, and support the need for a school-based self-management intervention to address this.

6.4 Final Conclusions

The level of poorly controlled asthma in children attending London secondary schools is of significant concern, I found evidence that poor control may be due to a number of barriers, both social and practical, which contribute to improper management of the condition. Although the study was a small sample and non-random, of asthmatic children in London, it still provides an indication to the disease burden of asthma unselected (by willingness of clinical centres to engage with research), young people, and it therefore provides some insights into the drivers for disproportionally high rates of asthma-related morbidity and mortality in the UK, compared with elsewhere in Europe. My findings support the current literature evidencing high rates of poorly controlled asthma, and ineffective management strategies, in children. Thus, a school-based self-management intervention could be an effective means of improving asthma control, through improved awareness in schools and improved education for asthma sufferers.

In addition to bridging the gap in the current UK literature, this study has also demonstrated impact in several ways. First, the team have worked collaboratively with the Healthy London Partnership on an asthma toolkit for schools (found here: https://www.healthylondon.org/resource/london-asthma-toolkit/). This toolkit is an online resource for healthcare professionals, school staff, parents/guardians, and children and young people. Within the toolkit are a number of resources for individuals, including links to school asthma policies, latest evidence, video resources describing what asthma is, what to do in an emergency, downloadable PDF files of asthma action plans, to support the management of asthma away from the clinical environment. The research team have worked with the Healthy London Partnership to develop the school's component of the toolkit. Included within this are an asthma board game, to be included as part of the intervention to teach children about when to use asthma medication. The Healthy London Partnership also acted in an advisory role to support the development of the intervention to be piloted in schools. During the piloting of the intervention, the Healthy London Partnership will support the research team to disseminate information about the project and aid with the recruitment of schools through including information about the project on their website and on their twitter account.

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Appendices

Appendix 1: Parental Information and Withdrawal Form:

Questionnaire

PARENT INFORMATION SHEET version 1.7 07.01.2015

To be read by parents and the young person at the same time

Dear Parent or Guardian

Your child is being invited to take part in a research study. Before you decide whether or not to agree to your child to taking part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and discuss it with others if you wish.

- PART 1: Tells you the purpose of this study and what will happen to your child if they take part.
- PART 2: Gives you more detailed information about the conduct of the study.
- PART 3: Asks if you agree that your child takes part in the study.
- PART 4: Gives you a withdrawal form to fill in and send back to us if you do not want your child to fill out a questionnaire.

Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish for your child to take part.

PART 1: Purpose of this study and what will happen to your child if they take part.

What is the purpose of the study?

This study aims to see how much asthma has an effect on the school life of children and young people. We are hoping to recruit around 560 young people to help us answer this question.

Why has my child been chosen?

Your child has been asked to take part because their school, youth forum or clinic has agreed to take part in the study.

Does my child have to take part?

No. It is up to you and your child to decide whether or not to take part. If you and your child decide to take part you are free to withdraw them from the study at any time without giving a reason. If you withdraw your child, unless you object, we will still keep records relating to their participation up to that point, as this is valuable to the study. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of any care you or your child may require from us in the future.

What will happen to my child if they take part?

Trained researchers will be coming to your child's school in the summer or autumn term to ask your child to complete an online questionnaire, which we expect will take no longer than 20-30 minutes. We will also work with your child's school to offer educational resources and opportunities from the research team.

Most children get information about this study through their school. Your child may however have been given information about this study via their asthma clinic or the Centre of the Cell. In this case they will be invited to Barts and The London School of Medicine and Dentistry to take part in the online questionnaire.

Young people will log on to a specially-designed website using their email address (or a unique username). They will then be able to complete the questionnaire. The questionnaire will collect information on;

1. Demographics (e.g. Age, ethnicity, location)
2. Asthma control (using a validated 'Asthma Control Test™')
3. Use of asthma medication
4. Unplanned medical attention
5. Asthma at school
6. Smoking and parental smoking
7. Emotional and behavioural well-being (using a validated 'Me & My School' test)

We will also ask your child's school for information about their attendance and sick leave. This information will be very helpful in working out whether asthma has an impact on attendance.

What do I have to do?

If you are happy for your child to take part in our research project you don't need to do anything. If you do not want your child to take part in this project please fill out the withdrawal form at the bottom of this information and hand it back to your child's teacher. On the day we visit your child's school or they come to the medical school your child can then take part in the questionnaire if they are still happy to do so.

What are the disadvantages and risks of taking part?

We do not anticipate any risks from taking part in the study. We will work with schools to avoid disruption to school timetables.

What are the possible benefits of taking part?

We hope children and families will benefit from increased knowledge and understanding of asthma research. We also hope that the results of our research will aid us in designing an intervention to help children with asthma improve their engagement at school.

What happens when the research study stops?

Your child's anonymised data will be analysed and published in a medical journal.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question. Our contact details can be found at the bottom of this sheet. If you remain unhappy and wish to complain formally, you can do this through either the NHS Complaints Procedure (details can be found under: http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/Pages/NHScomplaints.aspx). You can also contact the Patient Advice and Liaison Service (see contact details below) or the Joint Research Management Office (JRMO) at Barts and The London School of Medicine and Dentistry (which is part of Queen Mary, University of London).

Will my child taking part in this study be kept confidential?

Yes. All the information about your child's participation in this study will be kept confidential. The details are included in Part 2.

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you would like your child to participate, please continue to read the additional information in Part 2 before making any decision.

PART 2: Further details about the conduct of the study

What if new information becomes available?

Sometimes during the course of a study, new information becomes available on the procedures that are being studied (such as new techniques for collecting information). If this happens, we will tell you about it and discuss with you whether you want to or should allow your child to continue in the study. If you decide to withdraw, you and your child will suffer no adverse effects as a result. If you decide your child should continue in the study you will be asked to sign a withdrawal form. On receiving new information, we might consider it to be in your child's best interests to withdraw them from the study. If so, we will explain the reasons and arrange for their care to continue. If the study is stopped for any other reason, you will be told why.

What will happen if I don't want my child to carry on with the study?

We will seek your permission to include your child's results within the study. We will not do so without your permission.

Will my child's part in this study be kept confidential?

The records obtained while they are in this study as well as related health and attendance records will remain strictly confidential at all times. The information will be held securely on paper and electronically at the research centre and on secure servers in the UK under the provisions of the 1998 Data Protection Act. Their name will not be passed to anyone else outside the research team or the sponsor. They will be allocated a trial number, which will be used as a code to identify them on all trial forms.

Their questionnaire results and records will be available to researchers authorised to work on the trial but may also need to be made available to people authorised by the Research Sponsor, which is the organisation responsible for ensuring that the study is carried out correctly.

The information collected about your child may also be shown to authorised people from the UK Regulatory Authority and Independent Ethics Committee; this is to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to you and your child as a research participant.

If you withdraw consent from further study involvement, unless you object, your child's data will remain on file and will be included in the final study analysis.

In line with Good Clinical Practice guidelines, at the end of the study, your child's data will be securely archived for a minimum of 20 years. Arrangements for confidential destruction will then be made.

What will happen to any information my child gives?

Information will be stored and processed as stated above.

What will happen to the results of this study?

The results of the study will be available after it finishes and will usually be published in a medical journal or presented at a scientific conference. The data will be anonymous and none of the children involved will be identified in any report or publication.

How can I access the results of the study?

We aim to inform you and your child about the overall results via written information and presentations. Should you or your child in addition wish to see the results, or the publication, please ask the research team. We will however not be able to give access to individual results, as the information is confidential.

Who is organising and funding this study?

The study is co-sponsored by Barts and the London School of Medicine and Dentistry, and it is funded by the National Institute for Health Research's Collaboration for Leadership in Health Research and Care North Thames (http://www.uclpartners.com/our-work/nihr-collaboration-for-leadership-in-applied-health-research-and-care).

Who has reviewed the study?

This study was given favourable ethical opinion for conduct in the NHS by the National Research Ethics Service Committee South West – Exeter (http://www.nres.nhs.uk/contacts/nres-committee-directory/?entryid27=18577).

Please contact us for further information

You are encouraged to ask any questions you wish, before, during or after the study. If you wish to read the research on which this study is based, please ask the research team. If you require any further information or have any concerns while taking part in the study please contact the research team (contact details are at the end of this sheet).

Thank you for taking the time to read this information sheet and to consider this study.

Contact Details:

Research Team:

Chief Investigator: Professor Jonathan Grigg, 07787 550775, j.grigg@qmul.ac.uk

Outreach and Learning Officer: Dr Gioia Mosler, 020 7882 2361, g.mosler@qmul.ac.uk

PhD Student: Katherine Harris, 020 7882 2361, k.harris@qmul.ac.uk

Research Team Address:

Centre for Paediatrics

The Blizard Institute

Blizard Building

4 Newark Street

London E1 2AT

For advice about taking part in research in the NHS:

INVOLVE
Wessex House
Upper Market Street
Eastleigh
Hampshire
SO50 9FD

Telephone: 023 8065 1088
Textphone: 023 8062 6239
Fax: 023 8065 2885

Email: admin@invo.org.uk

For advice about research and patient issues at The Royal London Hospital and Barts Health NHS Trust:

Patient Advice and Liaison Service (PALS):

Ground Floor, Front Block
The Royal London Hospital
Whitechapel Road
London E1 1BB

Tel: 020 3594 2040

E-mail: pals@bartshealth.nhs.uk

PART 3: Do you agree that your child takes part in the study?

We hope you and your child are happy to take part in our research project. If you agree for your child to take part, then you don't need to do anything. You should keep this information sheet as reference in case you or your child have questions later on.

If you do not want your child to take part in this project please fill out the withdrawal form below and return it to your child's school or directly to the researchers.

PART 4: Withdrawal Form

You only need to complete this form if you do not wish your child to take part in the study.

If you are happy for your child to take part you don't need to do anything.

If you **do not** want your child to take part (please tick):

*I wish to **withdraw** my child from this study* ☐

Child's
name:…….....**.....**

Parent or carer's name:
……

Signature:…….....

Date:
…….....

Completed forms should be returned to the child's school or to one of the researchers.

To be filled out by researcher:

Researchers Name: ……

Researcher's Signature: ……..

A copy of all filled out forms will be filed with the study records and one may be sent to the Research Sponsor.

Appendix 2: Participant Information and Assent: Questionnaire

School-based Asthma Project
YOUNG PERSON INFORMATION SHEET: AGE 12-16
To be read by parents and the young person at the same time

Hello!

We are asking if you would join in a research project to find the answer to the question, "how much difference does asthma make to your school life?"

Before you decide if you want to join in, it's important to understand why the research is being done and what happens if you take part. Please take time to read the following information carefully, and discuss it with others if you want to.

Part 1: Why we do this research and what happens if you take part

WHY ARE WE DOING THIS RESEARCH?

Asthma affects lots of children and young people. We are trying to find out more about how asthma can effect young people at school. Our research project will hopefully show us how we could make school life better for young people with asthma.

WHY ME?

We want to involve children and young people who have asthma and attend secondary school, like you. We think the questions we ask are best understood by people with asthma of your age. We hope to include around 560 young people in the research.

DO I HAVE TO TAKE PART?

No. It is up to you. We will ask you to write down if you agree to take part in an assent (agreement) form. We will give you a copy of this information sheet and your signed form to keep. You are free to stop taking part at any time during the research without giving a reason. If you decide to stop, this will not affect how people help you if you ever need to go to hospital – it's your choice and we don't mind.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

We are going to come to your school and if you are interested in taking part in our research we will ask you if you can answer some questions on a computer. We will work with your school and may even give you a fun lesson about medical research.

If you did not hear about this project in school, but from your asthma clinic or the Centre of the Cell, we will invite you to Barts and The London School of Medicine and Dentistry to take part in the online questionnaire.

WHAT WILL I BE ASKED TO DO?

If you chose to take part, we will ask you to fill in an assent (agreement) form. Then we will ask you to complete an online questionnaire we have on a specially-made website. You will log on to the website using your email address (or a unique username). Then you will be able to

complete the questionnaire. Answering the questions will take no longer than 20 minutes and will ask you about:

1. General questions (for example age, ethnicity, and location)
2. Asthma control
3. Use of asthma medication
4. Unplanned visits to doctors or hospitals
5. Asthma at school
6. Smoking and smoking in your home
7. Emotional and behavioural well-being

We will also ask your school for information about your attendance and sick leave. This information will be very helpful in working out whether asthma has an impact on school attendance. If you would prefer us not to collect this information from the school, you can say this on the assent (agreement) form.

WILL THIS HELP ME?

We cannot promise the study will help you, but the information we get might help us understand how asthma affects children and young people's school life.

Thank you for taking time to read this information sheet – if you are still interested please read part 2.

Part 2: Further information

WHAT HAPPENS WHEN THE RESEARCH PROJECT STOPS?

We feel it is unlikely that the project stops, but if the study stops we will tell you about it and why this happend.

WHAT HAPPENS IF THERE IS A PROBLEM OR SOMETHING GOES WRONG?

If you are worried about any part of this study, you should speak with the researchers who will do their best to answer your question (their phone number and email is written at the bottom of this information). You can also ask your parents or teacher to contact the researchers for you. Your parents also have information how to contact other people, for example from the NHS (National Health Service), who can help if there is a problem.

WHAT WILL YOU DO WITH THE INFORMATION?

The information that you give us in the questionnaire will be changed to protect your name and who you are by changing information into a secret code. We will then keep it in a secure server (a big computer) in the UK. Any printed or written information will be kept at the research institute at Barts and The London School of Medicine and Dentistry. Only members of the research team will be able to look at the data on this server as it will be protected with passwords and 'firewalls'. The server will have a special certificate to prove the information is safe. When we have analysed the information we need to store the data for 20 years, just in case the information needs to be checked.

WILL I BE ABLE TO SEE THE INFORMATION YOU COLLECT?

When our project is finished we want to make the results public in a science paper. We also want to send you information about the results or show you a presentation. You can call or email us, if

you want to know more about the results. All results we will show are for groups of young people. We will not show you your own answers or answers of your friend, as they are secret.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

The study is co-sponsored by Barts and the London School of Medicine and it is funded by the National Institute for Health Research's Collaboration for Leadership in Health Research and Care North Thames (http://www.uclpartners.com/our-work/nihr-collaboration-for-leadership-in-applied-health-research-and-care is their web address).

WHO HAS REVIEWED THE STUDY?

Before any research can start it is checked by an independent Research Ethics Committee. They make sure that the research is fair. This study was checked by the National Research Ethics Service Committee South West – Exeter (http://www.nres.nhs.uk/contacts/nres-committee-directory/?entryid27=18577).

Thank you for reading this – please ask any questions if you want to.

CONTACT DETAILS

Gioia Mosler (Outreach and Learning Officer)

Telephone 020 7882 2361 **Email: g.mosler@qmul.ac.uk**

ASSENT FORM FOR YOUNG PERSON

To be completed by the child/young person and their parent/guardian

Child (or if unable, parent on their behalf) /young person to circle all they agree with:

Has somebody else explained this project to you? Yes/No

Do you understand what this project is about? Yes/No

Have you asked all the questions you want? Yes/No

Have you had your questions answered in a way you understand? Yes/No

Do you understand it is OK to stop taking part at any time? Yes/No

Are you happy to take part? Yes/No

If any answers are 'no' or you don't want to take part, don't sign your name!

If you do want to take part, you can write your name below

Your name

Date:

The person who explained this project to you needs to sign too:

Print Name:

Sign:

Date:

Thank you for your help.

Appendix 3: Questionnaire

Registration and Agreement to take part

First Name(s): _____

Last Name: _____

Email: _____

Date of Birth: _____

Many thanks for taking the time to complete the questionnaire.

This questionnaire asks about you, your asthma and how it affects your school life. Your answers are important to us as they will help with research into how we can help young people with asthma have a better time at school.

The questionnaire will take no longer than 20-30 minutes and will ask you about:

- General information (e.g. age, what area you live in etc.)
- How well your asthma is controlled
- Use of asthma medication
- Unplanned medical attention
- Asthma at school
- Smoking and parental smoking
- Emotional and behavioural well-being

We will also ask your school for information about your attendance and sick leave. This information will be very helpful in working out whether asthma has an impact on attendance. If you would prefer us not to collect this information from the school, you can indicate this below.

All the information you give us will be kept in a secure database by our research team. Everything you tell us will be kept strictly confidential and at no time will we share any of your personal details with anybody not connected to the research.

If you have any questions about the survey or our research, please contact us at g.mosler@qmul.ac.uk.

I declare that (please tick)

- ○ I have read the study information and any questions I had about the study were answered.
- ○ I understand that I can stop taking part at any time.
- ○ I agree for the research team to collect information from my school.
- ○ I am happy to take part in the study.

Section 1 (Personal details)

1. Are you male or female?

○ Male

- Female

2. How old are you?

3. How would you describe your ethnicity?

- White
- Black
- South Asian (e.g. Indian, Bangladeshi, Pakistani)
- East Asian (e.g. Chinese, Japanese, Korean)
- Mixed
- Other:

4. What's your home postcode? Please write the first part of your postcode (e.g. E14) or your full postcode (e.g. E14 2DR):

5. Do you have any long-term health conditions other than your asthma?

If the answer is yes please tick 'other' and describe your condition(s) in the text box

- No

Other:

Section 2: Asthma Control Test

6. In the past 4 weeks, how much of the time did your asthma keep you from getting as much done at work, school or home?

- All of the time
- Most of the time
- Some of the time
- A little of the time
- None of the time

7. In the past 4 weeks, how often have you had shortness of breath?

- More than once a day
- Once a day
- 3 to 6 times a day

- Once or twice a week
- Not at all

8. **In the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, chest tightness, shortness of breath) wake you up at night or earlier than usual in the morning?**

- 4 or more nights a week
- 2 to 3 nights a week
- Once a week
- Once or twice
- Not at all

9. **In the past 4 weeks, how often have you used your reliever inhaler (usually blue)?**

- 3 or more times per day
- 1 to 2 times per day
- 2 to 3 times per week
- Once a week or less
- Not at all

How would you rate your asthma control during the past 4 weeks?

- Not controlled at all
- Poorly controlled
- Somewhat controlled
- Well controlled
- Completely controlled

If you had completely controlled asthma in the last 4 weeks

1. Would you say your asthma has gone away
- Yes
- No

Section 3: Adherence

1. What type of inhaler(s) or other medications do you use on a regular basis? Only mention medication you use on a daily or weekly basis

Inhaler	Please cross:
Blue inhaler (salbutamol or Ventolin) 	
Red inhaler (ciclesonide or Alvesco) 	
Purple inhaler (fluticasone/salmeterol or Seretide) 	
Red/white inhaler (budesonide/formoterol or Symbicort) 	
Brown/white inhaler (budesonide or Pulmicort) 	
Brown inhaler (beclometasone or Becotide) 	
Orange inhaler (fluticasone or Flixotide) 	
Green inhaler (salmeterol or Serevent) 	
Steroid tablets: Prednisolone (usually pink)	
Theophylline tablets or Nuelin SA (usually white)	
LTRA tablet (montelukast or Singulair)	
I don't take any medication	
I have other inhalers or medications but I don't know their names	
Other:	

10. Do you use a spacer with any of your inhalers?

- Yes, I use a spacer with all of my inhalers
- Yes, I use a spacer with some of my inhalers
- No, I do not use a spacer with any of my inhalers

If you are using a spacer:

11. How often do you use your spacer?
    - All of the time
    - Most of the time
    - Some of the time
    - A little of the time
    - None of the time

If you are using a spacer

12. Know_02: What do you think your spacer is for
    - So I can see the spray from my inhaler: 0
    - To make sure I don't breeze in too much medication: 0
    - To help asthma medication go into my lungs: 1
    - To improve the taste: 0
    - Other: _____: 2

13. 14-Adh2a: Do you feel comfortable when you use your inhaler at school?

- Not at all comfortable: 1
- Hardly comfortable: 2
- Somewhat comfortable: 3
- Very comfortable: 4
- Completely comfortable: 5

14. 14-Adh2b: Do you feel comfortable when you use your inhaler outside of school (e.g. at home)?

- Not at all comfortable
- Hardly comfortable
- Somewhat comfortable
- Very comfortable
- Completely comfortable
- I do not need to use it in school

If you are taking a regular inhaler (e.g. brown inhaler)

11. **16-Adh4: Do you sometimes forget to take your regular preventer inhaler (e.g. brown inhaler)?**
    - All of the time: 1
    - Most of the time: 2
    - Some of the time: 3
    - A little of the time: 4
    - None of the time: 5

    I do not have a regular inhaler: 6

If you are taking regular preventer medication, e.g. brown inhaler

12. **17-Adh5: Do you sometimes miss your regular preventer inhaler (e.g. brown inhaler) on purpose?**
    - All of the time
    - Most of the time
    - Some of the time
    - A little of the time
    - None of the time

    18-Adh6: Would you like to tell us why?

If you are taking a regular preventer inhaler, e.g. brown inhaler

13. Know_01: What is your regular preventer inhaler for (e.g. brown inhaler):
    - To make my asthma go away for good: 0
    - To reduce symptoms during an asthma attack: 0
    - To stop me getting an infection: 0
    - To reduce the chances of me having an asthma attack: 1
    - Other: 2

If you are taking tables (e.g. steroid tablets or montelukast):

14. **9_ADH_tabC: Do you sometimes forget to take your tables when you should?**
    - All of the time: 1
    - Most of the time: 2
    - Some of the time: 3
    - A little of the time: 4
    - None of the time: 5

    I do not have tablets: 6

ADH_tabC2: Would you like to tell us why you might not take them?

If you are taking tables (e.g. steroid tablets or montelucast):

15. **15-Adh3b: How comfortable do you feel with taking your tablets?**
    - Not at all comfortable
    - Hardly comfortable
    - Somewhat comfortable
    - Very comfortable
    - Completely comfortable

16. **ADH_5b: Do you sometimes not use your blue reliever inhaler when you would need it?**

- All of the time
- Most of the time
- Some of the time
- A little of the time
- None of the time

ADH_7: Would you like to tell us why?

17. Know_03: When should you use a blue inhaler? Tick all that apply
    - When I wake up in the morning: a
    - Before PE: b
    - When I am wheezing: c
    - If I feel dizzy: d
    - When I am sneezing: e
    - When I have difficulty breathing: f

Section 4 Medical attention

11. How many times have you had an unplanned visit to your GP/doctor due to your asthma in the last month?

- 4 or more times
- 2-3 times
- 1-2 times
- Not at all

12. How many times have you had an unplanned visit to the hospital due to your asthma in the last month?

- 4 or more times
- 2-3 times

- 1-2 times
- Not at all

13. How many times have you had an unplanned visit to the school nurse/first-aider due to your asthma in the last month?

- 4 or more times
- 2-3 times
- 1-2 times
- Not at all

Section 5: School activity

11. How many times have you missed a whole day of school due to your asthma in the last month?

- 4 or more times
- 2-3 times
- 1-2 times
- Not at all

12. How many times have you missed part of a day at school due to your asthma in the last month?

- 4 or more times
- 2-3 times
- 1-2 times
- Not at all

13. How many times have you missed all or part of a regular class lesson due to your asthma in the last month?

- 4 or more times
- 2-3 times
- 1-2 times
- Not at all

14. How many times have you missed all or part of a P.E. lesson due to your asthma in the last month?

- 4 or more times
- 2-3 times
- 1-2 times
- Not at all

15. Do you feel that your asthma has a negative impact on how well you do in any of your classes or exams?

- My asthma doesn't have an impact at all
- My asthma hardly has an impact
- My asthma has a little bit of an impact
- My asthma has some impact
- My asthma has a big impact

Would you like to tell us more about any negative impacts your asthma has on your classes or exams?

Section 6: Lifestyle and smoking

11. Do you smoke? (This includes cigarettes/cigars, shisha/hookah, marijuana/weed etc.)
    - Yes, everyday
    - Yes, 5-6 days a week
    - Yes, 3-4 days a week
    - Yes, 1-2 days a week
    - Yes, less than once a week
    - No, not at all

12. Do your parents/carers or other people you live with smoke at the moment?
    - Yes
    - No

If your parents/carers or other people you live with don't smoke now,

13. Did any of them use to smoke at any time?
    - Yes
    - No

Section 7: Emotion and behavior

11. Are you happy to answer some questions about how you feel at school?
(It would be helpful to our research if you answered a few questions about your emotions and behavior and bullying at school. Answering these questions will allow us to work out whether or not it would be useful to offer young people with asthma support with their emotions and behavior)

If you are happy to continue, below is a questionnaire which is going to ask you how you feel. There are no right or wrong answers. You should just pick the answer which is best for you.

	Always	Sometimes	Never
I feel lonely			
I cry a lot			
I am unhappy			
Nobody likes me			
I worry a lot			
I have problems sleeping			
I wake up in the night			
I am shy			
I feel scared			
I worry when I am at school			
I get very angry			
I lose my temper			
I hit out when I am angry			
I do things to hurt people			
I am calm			
I break things on purpose			

12. Have you ever been teased, made fun of or bullied because of your asthma?

- ○ I've been bullied all the time because of my asthma
- ○ I've been bullied a lot because of my asthma
- ○ I've been bullied a little bit because of my asthma
- ○ I've hardly been bullied because of my asthma
- ○ I've never been bullied because of my asthma
- ○ Rather not say

Appendix 4: Table of Responses and Missing Data for Questionnaire

Question	Answer	Total Responses	Missing Data N (%)
Asthma Control Test			
In the past 4 weeks, how much time did your asthma keep you from getting as much done at work, school, or home?		**766**	**0**
	All the time Most of the time Some of the time A little of the time None of the time		
In the past 4 weeks, how often have you had shortness of breath?		**766**	**0**
	More than once a day Once a day 3-6 times a day Once or twice a week Not at all		
In the past 4 weeks, how often did your asthma symptoms wake you up at night or earlier than usual in the morning?		**766**	**0**
	4+ nights a week 2-3 nights a week Once a week Once or twice Not at all		
In the past 4 weeks, how often have you used your reliever inhaler (usually blue)?		**766**	**0**
	3+ times a day 1-2 times a day 2-3 times a week Once a week or less Not at all		
How would you rate your asthma control during the past 4 weeks?		**766**	**0**
	Not controlled at all Poorly controlled Somewhat controlled Well controlled Completely controlled		
If you had completely controlled asthma in the last 4 weeks: Would you say your asthma has gone away?			
	Yes No		
Medication Adherence			
What type of inhaler(s) do you use on a regular basis? Only mention medication you use on a daily or weekly basis		**766**	**0**
Do you use a spacer with any of your inhalers?		**762**	**4 (0.5)**
	Yes, I use a spacer with all of my inhalers		

	Yes, I use a spacer with some of my inhalers No, I do not use a spacer with any of my inhalers		
If you are using a spacer: How often do you use your spacer?		**310**	**1 (0.3)**
	All of the time Most of the time Some of the time A little of the time None of the time		
If you are using a spacer: What do you think your spacer is for?		**311**	**0**
Do you feel comfortable when you use your inhaler at school?		**762**	**4 (0.5)**
	Not at all comfortable Hardly comfortable Somewhat comfortable Very comfortable Completely comfortable I do not need to use it in school		
Do you feel comfortable when you use your inhaler outside school (e.g. at home)?		**762**	**4 (0.5)**
	Not at all comfortable Hardly comfortable Somewhat comfortable Very comfortable Completely comfortable		
If you are taking a preventer inhaler: Do you sometimes forget to take your preventer inhaler?		**414**	**9 (2.1)**
	All of the time Most of the time Some of the time A little of the time None of the time I do not have a regular inhaler		
If you are taking a preventer inhaler: Do you sometimes miss your preventer inhaler on purpose?		**391**	**32 (7.6)**
	All of the time Most of the time Some of the time A little of the time None of the time I do not have one		
If you are taking a preventer inhaler: What is your inhaler for?		**0**	**0**
If you are taking tablets: Do you sometimes forget to take your tablets?		**36**	**1 (2.7)**
	All of the time Most of the time Some of the time A little of the time None of the time		

If you are taking tablets: How comfortable do you feel with taking your tablets?		**34**	**3 (8.1)**
	Not at all comfortable		
	Hardly comfortable		
	Somewhat comfortable		
	Very comfortable		
	Completely comfortable		
Do you sometimes not use your blue inhaler when you would need it?		**606**	**42 (6.5)**
	All of the time		
	Most of the time		
	Some of the time		
	A little of the time		
	None of the time		
Medical Attention			
How many times have you had an unplanned visit to your GP/doctor due to your asthma in the last month?		**743**	**23 (3)**
	4 or more times		
	2-3 times		
	1-2 times		
	Not at all		
How many times have you had an unplanned visit to the hospital due to your asthma in the last month?		**743**	**23 (3)**
	4 or more times		
	2-3 times		
	1-2 times		
	Not at all		
How many times have you had an unplanned visit to the school nurse/first-aider due to your asthma in the last month?		**743**	**0**
	4 or more times		
	2-3 times		
	1-2 times		
	Not at all		
School Activity			
How many times have you missed a whole day of school due to your asthma in the last month?		**738**	**28 (3.7)**
	4 or more times		
	2-3 times		
	1-2 times		
	Not at all		
How many times have you missed part of a school day due to your asthma in the last month?		**738**	**28 (3.7)**
	4 or more times		
	2-3 times		
	1-2 times		
	Not at all		
How many times have you missed all or part of a regular lesson due to your asthma in the last month?		**738**	**28 (3.7)**
	4 or more times		
	2-3 times		
	1-2 times		
	Not at all		

How many times have you missed all or part of a PE lesson due to your asthma in the last month?		**738**	**28 (3.7)**
	4 or more times		
	2-3 times		
	1-2 times		
	Not at all		
Do you feel that your asthma has a negative impact on how well you do in any of your classes or exams?		**740**	**26 (3.4)**
	My asthma doesn't have an impact at all		
	My asthma hardly has an impact		
	My asthma has a little bit of an impact		
	My asthma has some impact		
	My asthma has a big impact		
Lifestyle and Smoking			
Do you smoke?		**766**	**0**
	Yes, everyday		
	Yes, 5-6 days a week		
	Yes, 3-4 days a week		
	Yes, 1-2 days a week		
	Yes, less than once a week		
	No, not at all		
Do your parents/carers/other people you live with smoke at the moment?		**734**	**32 (4.2)**
	Yes		
	No		
If your parents/carers other people you live with don't smoke now: Did any of them used to smoke at any time?		**543**	**6 (1.1)**
	Yes		
	No		
Emotion and Behaviour			
Are you happy to answer some questions about how you feel at school?		**732**	**34 (4.4)**
	Yes		
	No		
I feel lonely		**596**	**16 (2.6)**
	Always		
	Sometimes		
	Never		
I cry a lot		**596**	**16 (2.6)**
	Always		
	Sometimes		
	Never		
I am unhappy		**596**	**16 (2.6)**
	Always		
	Sometimes		
	Never		
Nobody likes me		**596**	**16 (2.6)**
	Always		
	Sometimes		
	Never		
I worry a lot		**596**	**16 (2.6)**
	Always		

	Sometimes Never		
I have problems sleeping		**596**	**16 (2.6)**
	Always Sometimes Never		
I wake up at night		**596**	**16 (2.6)**
	Always Sometimes Never		
I am shy		**596**	**16 (2.6)**
	Always Sometimes Never		
I feel scared		**596**	**16 (2.6)**
	Always Sometimes Never		
I worry when I am at school		**596**	**16 (2.6)**
	Always Sometimes Never		
I get very angry		**592**	**20 (3.3)**
	Always Sometimes Never		
I lose my temper		**592**	**20 (3.3)**
	Always Sometimes Never		
I hit out when I am angry		**592**	**20 (3.3)**
	Always Sometimes Never		
I do things to hurt people		**592**	**20 (3.3)**
	Always Sometimes Never		
I am calm		**577**	**35 (5.7)**
	Always Sometimes Never		
I break things on purpose		**592**	**20 (3.3)**
	Always Sometimes Never		
Have you ever been teased, made fun of, or bullied because of your asthma?		**594**	**18 (2.9)**
	I've been bullied all the time because of my asthma I've been bullied a lot because of my asthma I've been bullied a little bit because of my asthma I've hardly been bullied because of my asthma I've never been bullied because of my asthma Rather not say		

Appendix 5: Parental Information Sheet: Focus Groups

Information for Parents/ Carers

Dear parent/carer,

Your child has been invited to take part in a focus group about asthma at their school by researchers from Queen Mary University of London, in collaboration with Centre of the Cell.

We are scientists from Queen Mary University of London and work on a science project which tries to improve understanding of asthma in young people: the **School-based Asthma Project**.

We have previously visited your child's school and we collected information about their asthma, using an online questionnaire. The focus group is a discussion group in which we try to give young people with asthma a voice to determine the next steps for our research.

The focus group will take place in your child's school and will be led by researchers of the School-based Asthma Project (SAP). The focus group plans to meet a few times over the next 6 months. We will work with the school to make sure the focus groups will not have any impact on your child's other school activities (e.g. by organising lunchtime meetings).

What will we ask your child to do:

- We will ask for your child's opinions about the summarised results of the questionnaire and what they think the outcomes might mean.
- We will discuss what we know about asthma in young people and ask your child for their thoughts and opinions about future research we could do.

Benefits:

- Your child would get to know the scientists involved and learn about university research.
- We will try to make the meetings fun and interesting.
- We will provide for your child's wellbeing: free lunch if a meeting was scheduled during lunch time, and free snacks if your child missed any other break time.
- Your child will receive a certificate about their involvement in the focus group.

It is important for you to know:

- **Participation**: Your child does not have to take part in the focus group. You or your child can decide to stop participating in the group at any time.
- **Are there risks in taking part**: We do not anticipate any risks from taking part in the study. If you have a concern about any aspect of this study, you should contact the researchers. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure (see below for contact details).
- **Recording what was said:** In order to have a record of what was said, we would like to tape record some activities. Only the research team and the person who transcribes the tape will hear the recordings, which will be destroyed afterwards. No names will be written down when the recording is transcribed. In exceptional circumstances, for example in case of a medical emergency, information about what was said during the meeting related to this event may be disclosed to other professionals.

What will the information be used for: What was said in the focus group will be summarised and written into a report. The report we write will be used to guide the next steps of our research. We might also publish some information we collected in the focus group, for example quotes of what was said. Publications could include a research journal or our funder's website. Everything we write will be anonymous and your child's name will not be used.

Contact Details of our Research Team:
Chief Investigator:
Professor Jonathan Grigg, 07787 550775, j.grigg@qmul.ac.uk
Outreach and Learning Officer:
Dr Gioia Mosler, 020 7882 2361, g.mosler@qmul.ac.uk
PhD Student:
Katherine Harris, 020 7882 2361, k.harris@qmul.ac.uk
Research Team Address:
Centre for Paediatrics, the Blizard Institute, 4 Newark Street,
London E1 2AT

For advice about taking part in research in the NHS:
INVOLVE Wessex House Upper Market Street Eastleigh Hampshire SO50 9FD
Telephone: 023 8065 1088 **Textphone:** 023 8062 6239 **Fax:** 023 8065 2885
Email: **admin@invo.org.uk**

Appendix 6: Participant Information Sheet: Focus Groups

Tell us what you think!

Thank you again for taking part in our school-based Asthma Project questionnaire! From all the questionnaires we collected we know a lot more about asthma in young people like you. We would now like to invite you to take part in a FOCUS GROUP about our asthma research at your school.

The focus group is a discussion group where you meet us, the researchers, and others with asthma from your school.

1. We will show you some of summarised results of the questionnaire and want to hear from you what you think the outcomes mean.
2. We also want to hear your opinion about ideas for future asthma research we might want to do.

We will of course make the meetings fun as well, and we will bring some snacks to keep you going.

Before you decide whether you would like to take part or not it is important to understand why the focus group is organised and what it will involve. If you do not understand anything just ask us.

Who are we?
Our names are Dr Gioia Mosler and Ms Kate Harris and we work at Queen Mary University of London. We also work together with the Centre of the Cell, who develop school workshops and shows about health and medicine.

What are we doing?
The information we collected in the questionnaire gave us a lot of information about young people and their asthma. We now have some ideas about the next steps we can take to improve life with asthma for young people. Our future research will need to work for young people like you. It is therefore very important for us to hear what you think about the questionnaire results and to get your opinion on our ideas.

What will you be doing in the focus group?
During the meetings we would like to hear your opinion about our questionnaire results and what the next steps for our research could be. SAP focus group participant information v1.0, 20/05/15

When would the meetings take place?
We would like to meet with you a few times over the next 6 months. The meetings will take place during or after school and each meeting would be up to 1 hour long. We will work together with your teachers to find times when the meetings can take place.

Will you get anything for helping?
We will provide snacks during the meetings. You will also get a certificate for your participation to show that you've helped with some real science research.

How will we record what you say?
We would like to record some activities but we will ask you if this is OK first. We will only record your voice, you will not be filmed. This is so we don't forget what you have said. Only we and the person who types up the recording will hear it and the recording will be destroyed afterwards. We will not use your name in anything we write.

What will happen to the information we collect from you?
All your views and experiences will be put together with other information we have collected from other young people. The report we write will be used to determine the next steps of our research. We might also publish some information we have from focus groups for example in a research magazine.

What if I want to stop taking part?
You don't have to take part and you can stop taking part at any time.
If you want to ask any questions you can get in touch with me:
Dr Gioia Mosler, Outreach and Learning Officer
g.mosler@qmul.ac.uk
Tel: 020 7882 2361

Many thanks for your time!

Please contact your teacher [*contact teacher's name*] if you would like to take part in our focus group!

Appendix 7: Focus Group Structure

Item	Activity	Format
1	Icebreaker 'asthma is'	Game
2	Explanation of ACT	Discussion
3	Scenario: Perception of asthma control	Discussion
4	Perception of optimal asthma control	Discussion
5	Quick fire: Percentage of teenagers who miss preventer	Discussion
6	Explanations for non-adherence	Discussion
7	Attitudes about asthma management and peer awareness	Discussion
8	Knowledge	Discussion
9	Intervention ideas	Discussion

Appendix 8: Confidentiality Agreement

The following agreement applies to all persons carrying out transcription, translation, voiceovers, or any other type of service for The Transcription Agency (TTA).

1. **Confidential Information** - in the performance of my duties with TTA, I will be exposed to Confidential Information of both TTA and its clients. I understand that "Confidential Information" means information or material that is non-public and could therefore be damaging to TTA or its clients if it became public. This includes, but is not limited to:

(a) Classified information i.e. Official, Restricted, Confidential, Secret and Top Secret which is sensitive, government information that required protection from the public domain.
(b) technical information concerning TTA and its clients' products and services, including product/service know-how, formulas, designs, devices, diagrams, software code, test results, processes, inventions, research projects and product development, technical memoranda and correspondence;
(c) information concerning TTA and its clients' business, including cost information, profits, sales information, accounting and unpublished financial information, business plans, markets and marketing methods, market research, customer lists and customer/contact information, purchasing techniques, supplier lists and supplier information and advertising strategies;
(d) Information concerning TTA and its clients' employees/contacts, including salaries, strengths, weaknesses and skills;
(e) information submitted by TTA and its clients' customers, suppliers, employees, consultants or co-venture partners for study, market research, evaluation or use; and
(f) Any other information not generally known to the public which, if misused or disclosed, could reasonably be expected to adversely affect TTA and its clients' business.

2. **Non-disclosure of Confidential Information** - I shall keep TTA and its clients' Confidential Information, whether or not prepared or developed by myself, in the strictest confidence. I will not disclose such information to anyone outside of TTA without TTA's prior written consent. Nor will I make use of any Confidential Information for my own purposes or in any way other than that originally requested by TTA.

However, I shall have no obligation to treat as confidential any information which:
(a) Was in my possession or known to me, without an obligation to keep it confidential, before such information was disclosed to me by TTA;
(b) Is or becomes public knowledge through a source other than myself and through no fault of myself; or
(c) Is or becomes lawfully available to myself from a source other than TTA.
I will not, without the prior written consent of TTA, permit any of the Confidential Information:
(a) To be disclosed, except to TTA Management who may need to have such information; or
(b) To be discussed between myself and any family, friends and/or third parties; or
(c) To be copied or reproduced, or to be commercially exploited in any way; or
(d) To pass outside of my control

3. **Return of materials** - when I no longer provide services to TTA, for whatever reason, I will promptly deliver to TTA all originals and copies of all documents, records, software programs, media and other materials containing any Confidential Information which was required to be kept for the duration of my provision of services. I will also return to TTA all equipment, files, software programs and other personal property belonging to TTA's clients which was required to be kept for the duration of my provision of services. Any electronic materials will be securely and permanently removed from all applicable computer systems and transfer methods.

4. **Confidentiality obligation services provision of services** - my obligation to maintain the confidentiality and security of Confidential Information remains even after my provision of services with TTA ends and continues for so long as such Confidential Information remains a trade secret and/or solely the property of TTA and/or its client.

I understand that approval should first be obtained before any disclosure of other Confidential Information not addressed in this document, TTA's guidelines and/or policies and procedures, is made.
I also understand that the unauthorized disclosure of TTA and its clients' Confidential or Proprietary Information is grounds for disciplinary action, up to and including immediate dismissal and court action for breach of this confidentiality contract.
I hereby acknowledge, by my signature below, that I understand and will comply with all terms and requirements outlined in this Confidentiality Agreement document and the Data Protection Act as noted on http://www.legislation.gov.uk/
[Signature] [Date]
[Print Name]
[Full address, including country]
[Landline phone number] [Mobile/cell number]
[Email address]

Appendix 9: Code Log for Focus Group Analysis

Code	Sub-theme 1	Sub-theme 2	Sub-theme 3	Description
Asthma				This code refers to all discussions about general opinions of asthma
	Asthma control			Students discuss their perception of asthma control, and what it means for daily life
		Activity restrictions		Students talk about how asthma control influences ability to participate in activities
		Asthma management		Students discuss how their asthma management is affected by asthma control
		Experience of symptoms		Students mention the symptoms that might be associated with good and poor control
			Misperceptions	Some students demonstrated misperceptions about the symptoms that might be experienced with good and poor control
			Night-time symptoms	The students talked about how night-time symptoms vary according to how well controlled asthma is
		Medication use		The students discussed the differences in medication use, depending on how well controlled asthma is

			Misperceptions	Some students demonstrated incorrect knowledge about how asthma medication should be used in relation to asthma control
	Consequences			Students talked about the general consequences of living with asthma
		Activity limitations		Students talked about how having asthma can impact on their ability to participate in activities, not specific to asthma control
		Sleep disturbances		The students talked about how asthma can affect sleeping habits
	Embarrassment			The students discuss feeling embarrassed about having asthma
	Medication use			The students talked about the different medications that are associated with asthma
	Personal opinion			Students give some of their opinions on what asthma is
	Symptoms			Students mention some of the symptoms of asthma
Communication				This code refers to communicating with people regarding asthma

Healthcare Professionals		Students talk about communicating with healthcare professionals
	ACT scores	Students discuss the benefits of GP's knowing their ACT scores
	Language barriers	Students discuss some of the difficulties with the medical terminology
	Trust in the level of care	Students discuss continuity of care, and seeing different doctors
Non-asthmatics		The students talked about discussing asthma with people that don't have asthma
	Not being listened to	Students discuss not being listened to when they try to explain about their symptoms
	Not taking asthma seriously	Students mentioned that many people, including teachers and peers, do not take asthma seriously
	Reluctance to talk about asthma	The students talked about how uncomfortable some teenagers feel talking about their asthma
Undiagnosed cases		Students discuss some people with asthma symptoms who haven't had a diagnosis of asthma

		Barriers to diagnosis	The students talked about why some people do not see their GP even when they have symptoms of asthma
Knowledge			This code refers to knowledge and how it impacts on asthma management
	Causes		Students would like to know more about the causes of asthma
	General knowledge		The students wanted to learn more asthma general knowledge
	Medication		The students mentioned that they would like to know more about asthma medication and how it helps
	Preventing exacerbations		The students discussed knowing more about how to avoid asthma attacks
	Side-effects		The students wanted to learn more about the side-effects of asthma
	Triggers		The students wanted to learn more about asthma triggers
Medication			This code refers to asthma medication, specifically adherence
	Adherence		Students talk about barriers to adherence among teenagers
		Absence of symptoms	The students talked about how not having

	asthma symptoms is a barrier to adherence
Apathy	The students talk about not being bothered about their asthma medication
Embarrassment	The students discuss feeling embarrassed about using inhalers in front of people
Excuse to miss lessons	The students talk about how some people use their asthma as an excuse to get out of class
Forgetfulness	Students discuss how it is easy to forget medication
Inconvenience	The students talk about the difficulties of using their inhalers when they have other things to do
Inhaler efficacy	The students discuss their beliefs on the effectiveness of the medication
Reliance	The students discuss concerns over becoming reliant on their medication
Reluctance to use in public	Students discuss using inhalers in public
Side-effects	The students talk about some of the side-effects of asthma medication
Use of different medication	The students discuss the different inhalers, and

			how they are used
Psychological Impact			This code refers to the psychological impact of asthma
	Social		Students talk about the social concerns associated with having asthma as a teenager
		Bullying	Students discuss fears of bullying because of asthma
		Peer awareness	The students talk about the awareness of their peers
		Stigma	Students discuss some of the stigma faced

Appendix 10: Systematic Review Quantitative Search Strategy

#1 AST:MISC1
#2 MeSH DESCRIPTOR Asthma Explode All
#3 asthma*:ti,ab
#4 #1 or #2 or #3
#5 MeSH DESCRIPTOR Schools Explode All
#6 MeSH DESCRIPTOR School Health Services
#7 MeSH DESCRIPTOR School Nursing
#8 school*:ti,ab,kw
#9 academ*:ti,ab,kw
#10 colleg*:ti,ab,kw
#11 lesson*:ti,ab,kw
#12 pupil*:ti,ab,kw
#13 #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12
#14 MeSH DESCRIPTOR Self Care Explode All
#15 MeSH DESCRIPTOR Health Education Explode All
#16 MeSH DESCRIPTOR Case Management
#17 MeSH DESCRIPTOR Patient Education as Topic
#18 educat*:ti,ab,kw
#19 manag*:ti,ab,kw
#20 self-car*:ti,ab,kw
#21 self NEXT car*:ti,ab,kw
#22 train*:ti,ab,kw
#23 instruct*:ti,ab,kw
#24 teach*:ti,ab,kw
#25 patient-cent*:ti,ab,kw
#26 patient NEXT cent*:ti,ab,kw
#27 MeSH DESCRIPTOR Patient-Centered Care
#28 patient-focus*:ti,ab,kw
#29 patient NEXT focus*:ti,ab,kw
#30 coach*:ti,ab,kw
#31 skill*:ti,ab,kw
#32 knowledge NEXT develop*:ti,ab,kw
#33 tutor*:ti,ab,kw
#34 #14 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33
#35 #4 AND #13 AND #34

Appendix 11: Systematic Review Process Evaluation Search Strategy

Cochrane Database of Systematic Reviews

#1 MeSH Descriptor Asthma explode all
#2 Asthma*
#3 #1 or #2
#4 MeSH descriptor Schools explode all
#5 MeSH descriptor School Health Services
#6 MeSH descriptor School Nursing (nothing available in mesh term, school nursing searched in KW, TI and AB)
#7 school*
#8 academ*
#9 colleg*
#10 lesson*
#11 pupil*
#12 #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11
#13 MeSH descriptor Self Care explode all
#14 MeSH descriptor Health Education explode all
#15 MeSH descriptor Case Management
#16 MeSH descriptor Patient Education as topic
#17 educat*
#18 manag*
#19 self-car*
#20 self NEXT car*
#21 train*
#22 instruct*
#23 teach*
#24 patient-cent*
#25 patient NEXT cent*
#26 MeSH descriptor Patient-Centred Care
#27 patient-focus*
#28 patient NEXT focus*
#29 coach*
#30 skill*
#31 knowledge NEXT develop
#32 tutor*
#33 #13 or #16 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32
#34 #3 AND #12 AND #33

EMBASE

#1 “Asthma”
#2 “Schools”
#3 “School health services”
#4 “School nursing”
#5 “School”
#6 “Academy”
#7 “Academic”
#8 “Academies”
#9 “College”
#10 “Colleges”
#11 “Lesson”

#12 “Lessons”
#13 “Pupil”
#14 “Pupils”
#15 #2 or #3 or #4 or #5 or #6 or ‘7 or #8 or #9 or #10 or #11 or #12 or #13 or ‘14
#16 “Self care”
#17 “Health Education”
#18 “Case management”
#19 “Patient education”
#20 “Educate”
#21 “Education”
#22 “Educator”
#23 “Manage”
#24 “Management”
#25 “Self-care”
#26 “Train”
#27 “Training”
#28 “Trainer”
#29 “Instruct”
#30 “Instructor”
#31 “Instruction”
#32 “Teach”
#33 “Teacher”
#34 “Patient-center”
#35 “Patient-centre”
#36 “Patient-centred care”
#37 “Patient-focus”
#38 “Patient focus”
#39 “Coach”
#40 “Skill”
#41 “Skills”
#42 “Knowledge develop*
#43 “Tutor”
#44 #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43
#45 #1 and #15 and #44

Web of Knowledge

#1 (Asthma)
#2 (Asthma*)
#3 #1 or #2
#4 (Schools)
#5 (Schools health services)
#6 (School nursing)
#7 (School*)
#8 (Academ*)
#9 (Colleg*)
#10 (Lesson*)
#11 (Pupil*)
#12 #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11
#13 (Self care)
#14 (Health education)
#15 (Case management)
#16 (Patient education)
#17 (Educat*)
#18 (Manag*)

#19 (Self-car*)
#20 (Self car*)
#21 (Train*)
#22 (Instruct*)
#23 (Teach*)
#24 (Patient-cent*)
#25 (Patient cent*)
#26 (Patient-centred care)
#27 (Patient-focus*)
#28 (Patient focus*
#29 (Coach*)
#30 (Skill*)
#31 (Knowledge develop*)
#32 (Tutor*)
#33 #13 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #31
#34 #3 and #12 and #33

DOPHER

Same strategy as Web of Knowledge

NIHR HTA

#1 “Asthma”
#2 “Asthma*”
#3 #1 or #2
#4 “Schools”
#5 “Schools health services”
#6 “School nursing”
#7 “School”
#8 “Academy”
#9 “Academies”
#10 “College”
#11 “Colleges”
#12 “Lesson*”
#13 “Pupil*”
#14 ‘4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13
#15 “Self care”
#16 “Health education”
#17 “Case management”
#18 “Patient education”
#19 “Educate”
#20 “Education”
#21 “Manage”
#22 “Management”
#23 “Self-care”
#24 “Self care”
#25 “Train”
#26 “Training”
#27 “Instruct”
#28 “Instructor”
#29 “Instruction”
#30 “Instructing”
#31 “Teach”
#32 “Teacher”
#33 “Teaching”

#34 “Patient-centered”
#35 “Patient centered”
#36 “Patient-centered care”
#37 “Patient-focus”
#38 “Patient focus”
#39 “Coach”
#40 “Coaching”
#41 “Skill”
#42 “Skills”
#43”Knowledge development”
#44 “Tutor”
#45 #13 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43
#46 #3 and #14 and #45

ASSIA

((SU.Exact.Explode
(“Boarding schools”
Or “Charter schools”
Or “City technology colleges”
Or “Classroom management”
Or “Classrooms”
Or “Comprehensive schools”
Or “Continuation high schools”
Or “Denominational schools”
Or “Elementary schools”
Or “Girls’ schools”
Or “Grant maintained schools”
Or “High schools”
Or “Hospital schools”
Or “Independent schools”
Or “Infant schools”
Or “International schools”
Or “Islamic schools”
Or “Jewish schools”
Or “Junior high schools”
Or “junior schools”
Or “Junior secondary schools”
Or “Kindergartens”
Or “Language schools”
Or “Middle schools”
Or “Missionary schools”
Or “Neighbourhood schools”
Or “Nursery schools”
Or “Preparatory schools”
Or “Preschools”
Or “Primary schools”
Or “Private schools”
Or “Protestant missionary schools”
Or “Public schools”
Or “Religious residential schools
Or “Religious schools”
Or “Residential schools”
Or “Roman catholic schools”
Or “Schools”

Or “Secondary schools”
Or “Special schools”
Or “Steiner schools”
Or “Summer schools”
Or “Sunday schools”
Or “Supplementary schools”
Or “Truancy”)
Or (school* or academ*)
Or (colleg* or lesson*
Or (SU.Exact.Explode(“School psychologists”)
Or SU.Exact.Explode(“School nurses”)
Or SU.Exact.Explode(“School psychology”)
Or SU.Exact.Explode(“School nursing”)
And SU.Exact.Explode(“Asthma”
Or “Chronic asthma”
Or “Occupational asthma”)
Or asthma*
And ((self-car* or (Self near/0 car*
Or educat*)
Or SU.Exact.Explode(“Selfcare”)
Or SU.Exact.Explode(“Alcohol education” or “behavioural health education” or “drug education” or “health education” or sexual health education”)
Or SU.Exact.Explode(“Patient education”)
Or SU.Exact.Explode(“Patient centredness”)
Or SU.Exact.Explode(“Patient care”))
Or SU.Exact.Explode(“Case management”)
Or (manag* or train*)
Or (instruct* or teach*)
Or (patient near/0 focus* or patient-focus*)
Or (coach* or skill*))
Or ((knowledge near/0 develop*)
Or tutor*))

CENTRAL

TI = title; AB = abstract’ KY = keywords
#1 MeSH descriptor Asthma explode all trees
#2 Asthma*: TI, AB, KY
#3 #1 or #2
#4 MeSH descriptor Schools explode all trees
#5 MeSH descriptor School Health Services explode all trees
#6 MeSH descriptor School nursing explode all trees
#7 School*: TI, AB, KY or Academ*: TI, AB, KY or Colleg*: TI, AB, KY or Lesson*: TI, AB, KY or Pupil*: TI, AB, KY
#8 #4 or #5 or #6 or #7
#9 Educat*: TI, AB, KY or Manag*: TI, AB, KY or Self-car*: TI, AB, KY or self NEXT car*: TI, AB, KY or Train*: TI, AB, KY or Instruct*: TI, AB, KY or Teach*: TI, AB, KY or Patient-cent*: TI, AB, KY or patient NEXT cent*: TI, AB, KY or Patient-focus: TI, AB, KY or Patient NEXT focus: TI, AB, KY or Coach*: TI, AB, KY or Skill*: TI, AB, KY or Knowledge NEXT develop*: TI, AB, KY or Tutor*: TI, AB, KY
#10 MeSH descriptor Self care explode all trees
#11 MeSH descriptor Health education explode all trees
#12 MeSH descriptor Case management explode all trees
#13 MeSH descriptor Patient education explode all trees
#14 MeSH descriptor Patient-centered care explode all trees
#15 #9 or #10 or #11 or #12 or #13 or #14
#16 #3 and #8 and #15

AMED

#1 exp Asthma/
#2 exp Schools/
#3 asthma*.mp. [mp = title, other title, abstract, heading words]
#4 #1 or #3
#5 exp School health services/
#6 exp School nursing/
#7 (School* or academ* or colleg* or lesson* or pupil*).mp.
#8 #2 or #5 or #6 or #7
#9 (educat* or manag* or self-car* or train* or instruct* or teach* or patient-cent* or coach* or skill* or tutor*).mp.
#10 ((self adj1 car*) or (patient adj1 cent*) or (patient adj1 focus*) or (knowledge adj1 develop*)).mp.
#11 exp Self care/
#12 exp Health education/
#13 exp Case management/
#14 exp Patient education/
#15 exp Patient centred care/
#16 #9 or #10 or #11 or #12 or #13 or #14 or #15
#17 #4 and #8 and #16
#18 from 17 keep 1-100
#19 Limit 18 to yr = 1995-current

PSYCINFO

Full search conducted

CINAHL

#1 asthma*
#2 (MH "Asthma+")
#3 (MH "Schools+") or (MH "School health services+") or (MH "School nursing+") or School* or Academ* or Colleg* or Lesson* or Pupil*
#4 (MH "Self Care+") or (MH "Health Education+") or (MH "Case Management+") or (MH "Patient education+") or Educat* or Manag* or Self-car* or Self n1 car* or Train* or Instruct* or Teach* or Patient-cent*
#5 Patient n1 cent* or (MH "Patient-centered care+") or Patient-focus* or Patient N1 focus* or Coach* or Skill* or Knowledge n1 develop* or Tutor*
#6 #4 or #5
#7 #1 or #2
#8 #3 and #6 and #7

PubMed

Search everywhere
(((“Asthma” [Mesh] or asthma*))
And (((“Schools” [Mesh])
Or “School health services” [Mesh])
Or “School nursing” [Mesh]
Or school*
Or academ*
Or colleg*
Or lesson*
Or pupil*))
And (((((“Self care” [Mesh])
Or “Health education” [Mesh]

Or “Case management” [Mesh])
Or “Patient education as topic” [Mesh])
Or “Patient-centered care” [Mesh]
Or Educat*
Or Manag*
Or Self-car*
Or Self n1 car*)
Or Train*
Or Instruct*
Or Teach*
Or Patient-cent*
Or (Patient n1 cent*)
Or Patient-focus*)
Or Patient n1 focus*
Or Coach*
Or Skill*
Or (Knowledge n1 develop*)
Or Tutor*)
And 1995
Search run as protocol (MESH terms consistent etc)
After 1/1/1995 filter applied

HMIC

Same strategy as AMED

IBSS

((SU.Exact.Explode
(“Boarding schools”
Or “Charter schools”
Or “City technology colleges”
Or “Classroom management”
Or “Classrooms”
Or “Comprehensive schools”
Or “Continuation high schools”
Or “Denominational schools”
Or “Elementary schools”
Or “Girls’ schools”
Or “Grant maintained schools”
Or “High schools”
Or “Hospital schools”
Or “Independent schools”
Or “Infant schools”
Or “International schools”
Or “Islamic schools”
Or “Jewish schools”
Or “Junior high schools”
Or “junior schools”
Or “Junior secondary schools”
Or “Kindergartens”
Or “Language schools”
Or “Middle schools”
Or “Missionary schools”
Or “Neighbourhood schools”
Or “Nursery schools”
Or “Preparatory schools”

Or “Preschools”
Or “Primary schools”
Or “Private schools”
Or “Protestant missionary schools”
Or “Public schools”
Or “Religious residential schools
Or “Religious schools”
Or “Residential schools”
Or “Roman catholic schools”
Or “Schools”
Or “Secondary schools”
Or “Special schools”
Or “Steiner schools”
Or “Summer schools”
Or “Sunday schools”
Or “Supplementary schools”
Or “Truancy”)
Or (school* or academ*)
Or (colleg* or lesson*
Or (SU.Exact.Explode(“School psychologists”)
Or SU.Exact.Explode(“School nurses”)
Or SU.Exact.Explode(“School psychology”)
Or SU.Exact.Explode(“School nursing”)
And SU.Exact.Explode(“Asthma”
Or “Chronic asthma”
Or “Occupational asthma”)
Or asthma*
And ((self-car* or (Self near/0 car*
Or educat*)
Or SU.Exact.Explode(“Selfcare”)
Or SU.Exact.Explode(“Alcohol education” or “behavioural health education” or “drug education” or “health education” or sexual health education”)
Or SU.Exact.Explode(“Patient education”)
Or SU.Exact.Explode(“Patient centredness”)
Or SU.Exact.Explode(“Patient care”))
Or SU.Exact.Explode(“Case management”)
Or (manag* or train*)
Or (instruct* or teach*)
Or (patient near/0 focus* or patient-focus*)
Or (Coach* or skill*))
Or ((Knowledge near/0 develop*)
Or tutor*))

SOCABS

Same strategy as IBSS

SPP

Same strategy as HMIC

NHS EED; DARE

#1 MeSH descriptor “asthma” explode all trees
#2 (Asthma*)
#3 #1 or #2
#4 MeSH descriptor “school nursing” explode all trees

#5 MeSH descriptor “school health services” explode all trees
#6 MeSH descriptor “schools” explode all trees
#7 (School*) or (Academ*) or (Colleg*)
#8 (Lesson*) or (Pupil*)
#9 MeSH descriptor “self care” explode all trees
#10 MeSH descriptor “health education” explode all trees
#11 MeSH descriptor “case management” explode all trees
#12 MeSH descriptor “patient education” as topic; explode all trees
#13 (Educat*) or (Manag*) or (Self-Car*)
#14 (Self near Car*) or (Train*) or (Instruct*)
#15 (Teach*) or (Patient-cent*) or (Patient near Cent*)
#16 (Patient-focus*) or (Coach*) or (Skill*)
#17 (Knowledge near Develop*) or (Tutor*)
#18 (School*) or (Academ*) or (Colleg*)
#19 (Lesson*) or (Pupil*)
#20 (Educat*) or (Manag*) or (Self-Car*)
#21 (Self near Car*) or (Train*) or (Instruct*)
#22 (Teach*) or (Patient-Cent*) or (Patient near cent*)
#23 (Patient-focus*) or (Patient near focus*) or (Coach*)
#24 (Skill*) or (Knowledge near develop*) or (Tutor*)
#25 #9 or #10 or #11 or #12 or #20 or #21 or #22 or #23 or #24
#26 #4 or #5 or #6 or #18 or #19
#27 #3 and #25 and #26

BIBLIOMAP

#1 Free text: “asthma*”
#2 Free text: “school*” or “academ*” or “colleg*” or “lesson*” or “pupil*”
#3 Free text: “educ*” or “manag*” or “self-car*” or “train*” or “instruct*” or “teach*” or “patient-cent*” or “patient-focus*” or “coach*” or “skill*” or “tutor*”
#4 Free text: “self car*” or “patient cent*” or “patient focus*” or “knowledge develop*”
#5 #3 or #4
#6 #1 and #3 and #5

Appendix 12a: Data Tables for Process Evaluation Models

Model One: Setting and Participant Characteristics

	Successful Intervention	School-based Health Centre	High School	Parents Involved	Teacher Training	Stakeholder Training
Joseph 2010	0.52	0.55	1	0	0	0
Kouba 2012	0.33	0.33	1	1	0	0
Dore-Stites 2007	0.67	0.66	0	1	0	0
Joseph 2013	1.00	0.55	1	0	0	0
Mujuru 2011	0.67	0.66	0	0	1	0
Henry 2004	0.83	0.33	1	0	1	0
Pike 2011	0.67	0.33	0	0	1	0
Spencer 2000	0.33	0.66	0	1	0	0
Engelke 2013	0.50	0.66	0.5	1	1	1
Splett 2006	0.50	1.00	0.5	0	1	1
Kintner 2012	0.83	0.66	1	1	0	1
Berg 2004	0.83	0.66	1	0	0	0
Howell 2005	0.33	0.75	0	1	0	0
Gerald 2006	0.33	0.55	0	0	0	0
Langenfeld 2010	0.33	0.66	0	0	1	0
Al-Sheyab 2012	0.83	0.33	1	0	0	0
Levy 2006	0.52	0.33	0	0	1	0
Terpstra 2012	1.00	0.66	0.66	1	0	0
Horner 2015	0.67	0.66	0	0	0	0
Bruzzese 2008	0.94	0.66	0.66	1	0	0
Lee 2011	0.50	0.66	0	0	0	0
Bruzzese 2004	0.33	0.55	1	0	0	1
Cicutto 2013	0.67	0.33	0	0	0	1
Brasler 2006	0.00	0.66	0.66	1	0	0
Crane 2014	0.50	0.33	0	0	0	0
Bruzzese 2011	0.88	0.55	1	0	0	1
Magzamen 2008	0.19	0.55	0.75	0	1	0

Model Two: Recruitment and Retention Processes

	Successful intervention	Provision of additional marketing materials	Provision of incentives	Make-up sessions provided	Reminders for activity attendance
Joseph 2010	0.52	1	1	0	0
Kouba 2012	0.33	1	0	1	0
Dore-Stites 2007	0.67	1	1	0	0
Joseph 2013	1.00	1	1	0	0
Mujuru 2011	0.67	0	0	0	1
Henry 2004	0.83	0	0	0	0
Pike 2011	0.67	0	0.5	0	0
Spencer 2000	0.33	1	0	0	0
Engelke 2013	0.50	0	0	0	0
Splett 2006	0.50	0	0	0	0
Kintner 2012	0.85	1	1	1	0
Berg 2004	0.83	0	1	0	0
Howell 2006	0.33	0	1	1	1
Gerald 2006	0.33	0	0	0	0
Langenfeld 2010	0.33	0	1	0	0
Al-Sheyab 2012	0.83	0	0	0	0
Levy 2006	0.52	0	0	0	0
Terpstra 2012	1.00	1	1	1	1
Horner 2015	0.67	0	0	0	0
Bruzzese 2008	0.94	0	0	1	0
Lee 2011	0.50	0	0.75	0	0
Bruzzese 2004	0.33	0	1	0	1
Cicutto 2013	0.67	0	0	1	0
Brasler 2006	0.00	1	1	1	1
Crane 2014	0.50	0	0	0	0
Bruzzese 2011	0.88	0	0	1	0
Magzamen 2008	0.19	1	1	0	1

Model Three: Curriculum, Pedagogy and Intervention Emphasis

	Successful Intervention	Curriculum: Forming Alliances and Monitoring Symptoms	Curriculum Reflected Learning about Asthma Triggers and Monitoring Symptoms	Emphasis on Intervention as Tailored or Personalised	Emphasis on Developing Personal Responsibility	Pedagogical Style Focussed on Interactive Methods	Diverse Pedagogical Style
Joseph et al (2010)	0.52	0	1	1	0	0	0
Kouba et al (2012)	0.33	0	0	0	1	0	0
Dore-Stites (2007)	0.67	1	0	0	1	0	0
Joseph et al (2013)	1.00	0	1	1	0	0	1
Mujuru et al (2011)	0.67	0	1	0	0	0	0
Henry et al (2004)	0.83	0	0	0	0	0	0
Pike et al (2011)	0.67	0	1	0	0	0	0
Spencer et al (2000)	0.33	0	0	0	0	1	0
Engelke et al (2013)	0.50	0	0	0	0	0	1
Splett et al (2006)	0.50	0	0	0	0	1	0
Kintner et al (2012)	0.83	0	1	0	0	0	0
Berg et al (2004)	0.83	0	1	1	0	0	0
Howell (2005)	0.33	0	1	0	0	0	0
Gerald et al (2006)	0.33	1	0	0	0	0	0
Cheung et al (2015)	0.33	0	0	0	1	0	0
Al-Sheyab	0.83	0	1	0	1	0	1

et al (2012)							
Levy et al (2006)	0.52	0	0	0	0	0	1
Terpstra et al (2012)	1.00	1	0	0	1	0	0
Horner et al (2015)	0.67	1	0	0	1	0	0
Bruzzese et al (2008)	0.94	0	1	0	1	0	0
Lee (2011)	0.50	0	0	0	0	0	1
Bruzzese et al (2004)	0.33	0	0	1	0	0	0
Cicutto et al (2013)	0.67	1	0	0	0	0	0
Brasler and Lewis (2006)	0.00	0	1	0	0	0	0
Crane et al (2015)	0.50	0	0	0	1	0	0
Bruzzese et al (2011)	0.88	0	0	1	0	0	0
Magzamen et al (2008)	0.19	0	1	0	0	0	0

Model Four: Modifiable Design Features

	Intervention success	Theory driven	Personalised or individualised sessions	Implemented during lesson time	Implemented during free time	School nurse involved in delivery
Joseph 2010	0.52	1	1	1	0.33	0
Kouba 2012	0.33	1	1	0	1	0
Dore-Stites 2007	0.67	1	0	0.33	0.33	0.66
Joseph 2013	1.00	1	1	0.75	0.75	0
Mujuru 2011	0.67	0	0	1	0	0
Henry 2004	0.83	0	0	1	0	0
Pike 2011	0.67	0	0	1	0	0
Spencer 2000	0.33	0	1	0.33	0.33	0.66
Engelke 2013	0.50	0	0.66	0.33	0.33	1
Splett 2006	0.50	0	1	0.33	0.33	1
Kintner 2012	0.83	1	0	1	1	0.66
Berg 2004	0.83	1	0.66	0.33	0.33	0.66
Howell 2005	0.33	1	1	0.33	0.33	0.66
Gerald 2006	0.33	0	0	1	0.33	0
Langenfeld 2010	0.33	0	1	0.33	0.33	1
Al-Sheyab 2012	0.83	1	0	0.33	0.33	1
Levy 2006	0.52	0	0.66	0.33	0.33	1
Terpstra 2012	1.00	1	0	0	1	0.66
Horner 2015	0.67	1	0	0	1	0
Bruzzese 2008	0.94	1	0	0.33	0.33	0.66
Lee 2011	0.50	1	0	1	0	0.66
Bruzzese 2004	0.33	1	1	0.75	0.75	0
Cicutto 2013	0.67	1	0	0	1	0
Brasler 2006	0.00	0	0	0.75	0.75	0.66
Crane 2014	0.50	1	0	0	1	0.66
Bruzzese 2011	0.88	1	1	0.33	0.33	0
Magzamen 2008	0.19	0	0	0	1	1

Model Five: Stakeholder Involvement and Engagement

	Successful intervention	School asthma policy	Good relationships/engagement with students	Good relationships/engagement with school nurses	Child satisfaction
Joseph 2010	0.52	0	0	0	0
Kouba 2012	0.33	0	0	0	0
Dore-Stites 2007	0.67	0	0.75	1	1
Joseph 2013	1.00	0	1	0	0
Mujuru 2011	0.67	0	0.25	0	0
Henry 2004	0.83	1	0	0	0
Pike 2011	0.67	0	0	0	0
Spencer 2000	0.33	0	1	1	0
Engelke 2013	0.50	1	1	0	0
Splett 2006	0.50	1	0	1	0
Kintner 2012	0.83	0	0.25	0	1
Berg 2004	0.83	0	0	0	1
Howell 2005	0.33	0	0.75	0.75	0.63333
Gerald 2006	0.33	0	0	0	0
Langenfeld 2010	0.33	1	0	1	0
Al-Sheyab 2012	0.83	0	0	0	0.63333
Levy 2006	0.52	1	0	0	0
Terpstra 2012	1.00	0	0.25	0	0
Horner 2015	0.67	0	0	0	0
Bruzzese 2008	0.94	0	1	0	1
Lee 2011	0.50	0	0	0	0
Bruzzese 2004	0.33	0	0	0	0.63333
Cicutto 2013	0.67	1	0		0
Brasler 2006	0.00	1	0	1	0.63333
Crane 2014	0.50	0	0	1	0
Bruzzese 2011	0.88	0	0	0	0
Magzamen 2008	0.19	0	0	0	0

Appendix 12b: Truth Tables for Process Evaluation Models

Model One: Setting and Participant Characteristics

	School health centre	High school	Parents involved	Teacher training	Stakeholder training	Outcome Code (based on consistency score)	Studies with membership in causal combination > 0.5	Consistency score with sub-set relationship	Proportional reduction in inconsistency	Studies
1	1	1	0	1	0	1	2	1	1	Bruzzese 2008; Terpstra 2012
2	1	0	1	0	0	1	1	1	1	Henry 2004
3	1	1	1	1	1	1	1	1	1	Kintner 2012
4	0	0	1	0	1	1	1	0.995	0.99	Cicutto 2013
5	0	0	0	0	0	1	2	0.918	0.588	Crane 2014; Pike 2011
6	1	0	0	0	0	1	1	0.889	0.811	Al-Sheyab 2012
7	1	1	0	0	1	0	2	0.865	0.662	Bruzzese 2004; Bruzzese 2011
8	1	1	0	0	0	0	4	0.852	0.761	Berg 2004; Joseph 2010; Joseph 2013; Magzamen 2008
9	0	1	0	0	0	0	4	0.845	0.543	Horner 2015; Langenfeld 2010; Lee 2011; Mujuru 2011
10	0	0	1	0	0	0	1	0.763	0.136	Levy 2006
11	0	1	1	0	0	0	1	0.754	0	Gerald 2006
12	1	0	0	1	0	0	1	0.751	0.647	Kouba 2012
13	0	1	0	1	0	0	3	0.73	0.56	Dore-Stites 2007; Howell 2005; Spencer 2000
14	1	1	1	1	0	0	1	0	0	Brasler 2006

Model Three: Curriculum, Pedagogy and Intervention Emphasis

	Curriculum: forming alliances/monitoring symptoms	Curriculum: asthma triggers/monitoring symptoms	Tailored/personalised intervention	Aim: developing personal responsibility	Pedagogical style focused on interactive methods	Diverse pedagogical style used	Outcome code	Studies with membership in causal combination >0.5	Consistency score with sub-set relationship	Proportional reduction in inconsistency	Studies
1	0	1	1	0	0	1	1	1	1	1	Joseph 2013
2	0	1	0	1	0	0	1	1	0.938	0.933	Bruzzese 2008
3	0	0	0	0	0	0	0	1	0.833	0.8	Henry 2004
4	0	1	0	1	0	1	0	1	0.833	0.8	Al-Sheyab 2012
5	1	0	0	1	0	0	0	3	0.778	0.714	Dore-Stites 2007; Horner 2015; Terpstra 2012
6	0	1	1	0	0	0	0	2	0.677	0.523	Berg 2004; Joseph 2010
7	0	0	1	0	0	0	0	2	0.604	0.486	Bruzzese 2004; Bruzzese 2011
8	0	0	0	0	0	1	0	3	0.507	0.027	Engelke 2013; Lee 2011; Levy 2006
9	1	0	0	0	0	0	0	2	0.5	0.25	Cicutto 2013;

											Gerald 2006
10	0	1	0	0	0	0	0	6	0.448	0.287	Brasler 2006; Howell 2005; Kintner 2012; Magzamen 2008; Mujuru 2011; Pike 2011
11	0	0	0	0	1	0	0	2	0.717	0	Spencer 2000; Splett 2006
12	0	0	0	1	0	0	0	3	0.389	0	Crane 2014; Kouba 2012; Langenfeld 2010

Model Four: Modifiable Design Features

Theory driven	Personalised or individual sessions	Implemented during lesson time	Implemented during free time	School nurse involved in delivery	Outcome code	Studies with membership in causal combination >0.5	Consistency score with sub-set relationship	Proportional reduction in inconsistency
1	0	0	0	1	1	2	1	1
1	0	0	0	0	1	1	1	1
1	0	1	1	1	1	1	1	1
1	1	0	0	0	1	1	0.996	0.993
1	0	0	1	1	1	1	0.931	0.816
1	1	1	0	0	1	2	0.931	0.872
1	0	1	0	1	1	1	0.903	0.729
1	1	1	1	0	0	2	0.852	0.729
1	0	0	1	0	0	2	0.833	0.706
1	1	0	0	1	0	2	0.753	0.602
1	1	0	1	0	0	1	0.732	0.481
0	0	1	0	0	0	5	0.659	0.035
0	1	0	0	1	0	0	4	0.683
0	0	1	1	1	0	0	1	0.05
0	0	0	1	1	0	0	1	0.444

Model Five: Stakeholder Involvement and Engagement

	School policy	Good parent relationship/engagement	Good school nurse relationship/engagement	Child satisfaction	Outcome code	Number of studies with membership in causal combination >0.5	Consistency score with sub-set relationship	Proportional reduction in inconsistency	Studies
1	0	1	0	0	1	1	1	1	Joseph 2013
2	0	1	0	1	1	1	0.958	0.939	Bruzzese 2008
3	0	0	0	1	1	4	0.857	0.786	Al-Sheyab 2012; Berg 2004; Bruzzese 2004; Kintner 2012
4	0	1	1	1	0	2	0.723	0.465	Dore-Stites 2007; Howell 2005
5	1	0	0	0	0	3	0.674	0.515	Cicutto 2013; Henry 2004; Levy 2006
6	0	0	0	0	0	10	0.615	0.405	Bruzzese 2011; Gerald 2006; Horner 2015; Joseph 2010; Kouba 2012; Lee 2011; Magzamen 2008; Mujuru 2011; Pike 2011; Terpstra 2012
7	0	0	1	0	0	1	0.6	0	Crane 2014
8	1	1	0	0	0	1	0.5	0	Engelke 2013
9	0	1	1	0	0	1	0.488	0	Spencer 2000
10	1	0	1	0	0	2	0.352	0	Langenfeld 2010; Splett 2006
11	1	0	1	1	0	1	0	0	Brasler 2006

Appendix 13: Intervention Protocol

Title: Multifaceted theory-based self-management intervention to improve adolescents' asthma control: A cluster randomised controlled trial (RCT)

Protocol version: 1.0

Date of Protocol: 7th December 2017

Grant Reference: MGU0400

REC Reference: QMERC2017/77

Date of Ethical Approval: 12th April 2018

Principal Investigator (PI): Professor Jonathan Grigg

Co-Investigator 1: Professor Chris Bonell[2]

Co-Investigator 2: Professor Chris Griffiths[3]

Co-Investigator 3: Dr Liz Steed[3]

Co-Investigator 4: Kate Harris[1]

Co-Investigator 5: Dr Gioia Mosler[1]

Organisations: (1) Genomics and Child Health, Blizard Institute, Barts and the London School of Medicine and Dentistry; (2) London School of Hygiene and Tropical Medicine; (3) Centre for Primary Care and Public Health, Barts and the London School of Medicine and Dentistry

1. Study Summary

Full Title	Multifaceted theory-based self-management intervention to improve adolescents' asthma control: A cluster randomised controlled trial
Short Title	My Asthma in School
Protocol Version	1.0
Protocol Date	7th December 2017
Methodology	Pilot cluster RCT
Study Duration	2 years
Study Centres	Barts and the London School of Medicine and Dentistry, Queen Mary, University of London; Centre for Primary Care and Public Health, Queen Mary, University of London
Primary Objectives	To test the effectiveness of an intervention to improve asthma control in adolescents with asthma, through a targeted school-based self-management intervention
Secondary Objectives	(1) Raise awareness of asthma in schools among peers; (2) Facilitate the capacity of young people to communicate about their asthma to heath care professionals
Number of Participants	At least 360 children with doctor-diagnosed asthma across all three groups (approximately 20 asthmatic children from 18 schools), accounting for a 15% attrition rate
Main Inclusion Criteria	Year 7 & 8 Secondary school children in Greater London
Statistical Methodology and Analysis	Descriptive statistics, Mann-Whitney U tests, chi-squared analysis

2. Table of Contents

3. Glossary of Terms and Abbreviations

Term	Acronym	Page Number
Principal Investigator	PI	1
United Kingdom	UK	6
Inhaled Corticosteroids	ICS	6
Long-Acting Beta-Agonists	LABA	6
Short-Acting Beta-Agonists	SABA	6
Asthma Control Test	ACT	6
General Practitioner	GP	7
Medical Research Council	MRC	7
Greenwich and Lewisham Young People's Theatre	GLYPT	9
Asthma UK Centre for Applied Research	AUKCAR	12
Self-Management Plans	SMPs	13
Standard Deviation	SD	16
Research Ethics Committee	REC	15
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Patient and Public Involvement	PPI	16
Joint Research and Management Office	JRMO	16

4. Rationale and Background

Approximately 1.1 million children and young people in the United Kingdom (UK) are living with asthma, making it the most common chronic disease in children in the UK. According to the Global Initiative for Asthma [2], people with good asthma control should not experience troublesome symptoms. Despite this, asthma-related morbidity and mortality in the UK is disproportionally higher than in most other western countries; however the reasons for this remain unclear. In the UK and Ireland, approximately 15% of the respective populations are living with asthma [17]. This is in comparison with the rest of Western Europe, where asthma prevalence is approximately 6% [59]. In England, asthma mortality among 5-34 year olds is approximately 3.2 per 100,000 asthmatics, compared with European nations such as Finland and Sweden, where mortality rates are 1.6 and 2.0 per 100,000 asthmatics, respectively [1]. According to the National Review of Asthma Deaths [14], asthma-related deaths in the UK are preventable in up to 65% of cases. Factors identified in the review, that have been found to be associated with asthma-related deaths, include poor medication adherence, as well as a poor understanding of the risks related to the condition, especially in children and young people.

Our recent observational study [258] evaluated current levels of asthma control and self-management in adolescents. The study, in combination with our earlier focus groups, informs about current levels of asthma control among adolescents in London, and existing barriers to successful self-management. Poor asthma control, poor medication adherence, and poor understanding of asthma were identified as unmet needs of secondary school children. We found that 45.7% of the secondary school children in our sample had suboptimal asthma control, as indicated by a score of 19 or less out of 25 on the Asthma Control Test (ACT), and 60.4% of students did not take their Inhaled Corticosteroids (ICS) $\pm$ Long-Acting Beta-Agonists (LABA) inhaler as prescribed; 30% of students did not take their Short-Acting Beta-Agonist (SABA) inhaler when they needed it [258]. The subsequent focus groups highlighted barriers to medication adherence among teenagers. The reported barriers included forgetfulness, incorrect or unhelpful medication beliefs, and social factors such as discomfort about taking medication at school due to embarrassment and bullying concerns. The focus groups also highlighted low levels of peer

awareness and perceived social stigma as a concern among teenagers. Concerns about communication with General Practitioner's (GP) were also highlighted. For example, some students expressed concern that they see a different GP each time they have an appointment, and each GP says something different. Moreover, some students felt that it was difficult to understand the medical terminology often used in consultations, which made it difficult to follow doctor recommendations.

A recent systematic review of school-based interventions, conducted by KH and JG with colleagues at the Institute of Education and Cochrane [200], conducted a process evaluation [175] and meta-analyses on included studies looking at school-based self-management interventions for children with asthma. The outcomes from this review identified that school-based self-management interventions are successful at improving children's outcomes across several areas, including reduced rates of unscheduled care, improved health-related Quality of life and improved medication use. The process evaluation component of the systematic review furthermore identified that a theoretical framework is an important component in intervention implementation success.

Improving asthma understanding, self-efficacy, and unhelpful beliefs towards asthma and it's treatment are key to improving adherence and self-management [9]. Better understanding and appropriate beliefs can empower teenagers to take control of their asthma, particularly when preparing for the transition to adult care. The effects of poor self-management and non-adherence can also last into adulthood, if a lack of self-management skills and awareness remains.

Following the findings above, and the Medical Research Council (MRC) framework for complex interventions [247], a preliminary theory-based multifaceted intervention has been developed. This draws on our earlier work [258] and theory. This aims to improve asthma self-management and control in young people. The development of the intervention is theory driven, and addresses barriers to successful self-management. The PRECEDE-PROCEED model was used conduct the initial diagnosis of social, epidemiological, educational and administrative diagnosis. We then used the behaviour change wheel [248] as a framework to translate identified behaviours into

specific interventions with specific translation into behaviour change techniques to maximise transparency of the intervention and understanding of the processes of action.

The intervention will engage asthmatic teenagers and their peers. This will be delivered in three components:

1. A theatre workshop for all year 7 and 8 students. The aim of this component is to raise awareness of asthma in schools among peers;
2. A series of four self-management workshops for asthmatic students. The aim of this component is to teach children with asthma about the condition, using interactive elements, including role plays and games. The students will complete a questionnaire, at the beginning and end of the session, and every few months for 12 months post-intervention, to test the effect of these workshops on their self-management behaviours. The questionnaire will include questions about asthma attitudes and beliefs, medication adherence, healthcare use, and school attendance. The students will also receive a resource pack to take home and go through with their parents, including a certificate of involvement and an 'asthma passport', which will include an asthma action plan and information about medication adherence;
3. We will contact the parents of the children and send them the healthcare use component of the questionnaire, to validate the responses provided by the children, as the data being collected is all self-report.

We will also continue testing different elements of the workshops in schools until the intervention is implemented.

5. Study Objectives

This study includes one primary objective, and two secondary objectives.

5.1 Primary Objective

The primary objective is to test the effectiveness of an intervention to improve asthma control in adolescents with asthma, through a targeted school-based self-management intervention.

5.2 Secondary Objectives

The secondary objective of this study is to raise awareness of asthma in schools among peers. This will be addressed through the delivery of a theatre workshop, in collaboration with Greenwich and Lewisham Young People's Theatre (GLYPT) Company.

6. Study Design

The study design is a cluster-randomised trial, with schools acting as the unit of allocation. There will be three intervention arms:

(1) Asthma workshop and theatre group

The asthma workshop and theatre group will receive the self-management workshops for asthmatic children and the theatre performance for the whole year group.

(2) Theatre only group

The "theatre only group" will receive the theatre performance only. The theatre only group was included as a treatment arm to identify whether raising awareness among peers was sufficient to change self-management behaviours among asthmatics, without the added self-management workshops.

(3) Control group

The control groups will receive usual care for the duration of the intervention.

The self-management workshops will take place in the interventions schools, over the course of one school day. The theatre performance will be delivered to students before the self-management workshops. Baseline data will be collected, followed by 3, 6 and 12 month follow-up post-intervention. This method of follow-up data collection will be tested with teenagers during the pilot study.

7. Recruitment

The target population for this study is children with asthma in years 7 and 8, who are attending secondary school in London. In our earlier study, school recruitment was initially local, through partner organisations (such as the Centre of the Cell). After initially limited uptake, most London secondary schools (in excess of 700) were contacted via email and invited to take part. The sample size was calculated, based on a power calculation, using Asthma Control Test (ACT) score as the

primary outcome measure. Adjusting for a 15% attrition rate, a minimum of 360 children are required for this study, from 18 schools (6 schools in each arm of the intervention; 20 students with asthma from each school). Maintaining allocation concealment, the schools will be randomised to one of the three intervention arms. Participation will be offered to all of our existing partner schools (n = 24), as well as all other schools in London who have not previously participated in our research. All schools will be randomised to one of the three arms of the study. Control schools will be offered the full intervention at the end of the trial.

The schools will be recruited via established recruitment strategies. This includes targeted emails and phone calls to teachers at each school to inform them of the research. The schools will be responsible for identifying eligible children (both asthmatic and non-asthmatic) and disseminating the information sheets and withdrawal forms to parents.

7.1 Inclusion Criteria

The inclusion criteria states that children with asthma will be eligible to participate if they have doctor-diagnosed asthma, are in years 7 or 8 at secondary school (aged 11 to 14 years), and are attending the secondary school in which the study is implemented.

For the theatre component of the study, which will be delivered to the whole year group (asthmatic and non-asthmatic children), students will be eligible if they are in years 7 or 8, and are attending the school at the time that the theatre workshop is delivered.

No inclusion criteria will be placed on schools, instead, state schools and private schools will be invited to participate. Children with special educational needs at participating schools will also be invited to participate, if they have capacity to provide assent. The research team will follow the school guidance for supporting these children (e.g. inviting their one-to-one support workers, if appropriate, to support the child through the study).

7.2 Exclusion Criteria

Students will not be eligible for participation in the workshops if they do not have asthma, as diagnosed by their doctor, they are not in years 7 or 8 at school, or they are not attending the school at the time that the intervention is delivered. Specialist units will be excluded from the study.

8. Summary of Investigational Plan

Already established partner schools, from the earlier school-based asthma project, will be invited to participate. A minimum of 360 children from at least ten schools are required. A minimum of 360 children with asthma will directly benefit from the intervention. Given a prevalence of 9%, approximately 1000 peers without asthma will also benefit from an increased understanding of life with asthma. If further schools are required, established recruitment strategies will be followed, including emails and telephone schools to designated teachers (e.g. head of science) in schools.

The intervention comprises two components. In the first component, a theatre workshop will be delivered to the whole of year groups 7 & 8, by collaborators at GLYPT, and aims to raise awareness of asthma in schools. The second component will be a series of educational workshops delivered to children in years 7 & 8 with asthma only, to improve asthma control through self-management.

Opt-out consent for the intervention will be obtained from all parents of children with asthma, followed by student assent, which will be collected from participating students on the morning of the intervention. For the children without asthma, consent to participate in the theatre workshop will be provided by the school as part of a learning tool. This consent procedure was considered the most appropriate as it was used in our earlier schools-based research. Feedback from teachers suggested that opt-in consent was too time consuming, and opt-out consent was their preferred method.

The results of this study will inform the development of a larger trial, to be delivered to UK secondary schools nationwide. The results of this trial will also influence national clinical guidance through the updating of the British Asthma Guidelines. The study will form a central element of the Asthma UK Centre for Applied Research's (AUKCAR) programme to reduce risk of asthma death.

9. Methodology

9.1 Outcome Measures

The primary outcome in this study is asthma control, which will be measured using the validated Asthma Control Test [68]. The secondary outcomes are medication adherence, which will be measured using the Medication Adherence Rating Scale [249]; unscheduled care, which will be measured using the scale used in our earlier study [258]; asthma attitudes, which will be measured using the Brief Illness Perception Questionnaire [250]; school absences, which will be measured using the scale used in our earlier study [258]; asthma knowledge, which will be measured using a scale adapted from an earlier study about asthma [251]; and beliefs about asthma medication, which will be measured using the Beliefs about Medicine questionnaire [252].

9.2 GLYPT Theatre Workshops

A drama workshop will be delivered to all students in years 7 and 8 in secondary schools, to facilitate awareness and understanding of asthma among the direct peer group. At the end of the theatre workshop, the main character will stay in role, and will encourage audience participation and discussion on the play. Earlier focus groups identified barriers to medication adherence among teenagers in schools, including a belief that their peers do not understand asthma. Through changing attitudes and awareness among peers at school, students with asthma should feel less concerned about the social barriers that currently prevent positive self-management behaviours.

9.3 Self-Management Workshops

A total of four self-management workshops will be delivered to children with asthma, following delivery of the theatre workshop. Each workshop will last approximately one hour, and will include a series of games, role play, media (films) and discussion. The main topics will include asthma general knowledge and understanding; GP communication; asthma triggers and symptoms; medication and emergency response; and self-management techniques and goal setting. Schools will also receive a toolkit, which will include emergency response posters, and advice on asthma friendly schools.

9.4 Statistical Analysis Plan

All of the outcomes in this study will be evaluated using the outcome measures outlined in section 10.1 of this protocol, and the findings from this study will be analysed quantitatively. Spearman's rank order correlation co-efficient will be used to assess the relationship between asthma control scores and other continuous variables (e.g. age). Chi-squared analyses and Mann-Whitney U tests will be used to look at whether differences in attitudes and knowledge exist between the asthmatic and non-asthmatic children, and the differences in outcomes between the asthmatic children in the three arms of the study. Chi-square analyses will also assess differences in outcomes across subgroups, including gender and ethnicity. All statistical analyses will be discussed with a statistician.

10. Safety Considerations and Ethics

10.1 Risks

Our previous work within schools did not highlight any risks or negative impact of taking part in our research. All parts of the intervention will be conducted in schools, therefore participating schools must enforce relevant health and safety practices. All members of the team will have up-to-date enhanced DBS checks prior to entering the schools. Participants will be reminded during the workshops that they can leave at any time. All young people who have any concerns or further questions beyond the scope of the intervention will be signposted to online asthma information (for example the Asthma UK website), and will be encouraged to contact their GP.

10.2 Data protection and confidentiality

All data that is collected will be stored securely behind two locked doors, and will be accessible only by members of the research team as on 'as needs' basis. Questionnaire data will be stored electronically on QMUL computers, with the relevant electronic security certificates and protocols installed. All student identifiable data will be substituted with an anonymous identifier for the purposes of analysis. All participant data will remain confidential, and our procedures for handling, processing, storing and destroying data will be compliant with the Data Protection Act 1998.

10.3 Data monitoring

Random audits of the data quality will be performed by members of the investigating team (KH and GM), under the supervision of the PI.

10.4 Premature termination of the study

This study is scheduled to run for two years. It is not expected that there will be any cause for premature termination of the study.

10.5 Ethical review

The protocol will be reviewed by the Queen Mary University of London ethics committee.

11. Study Timetable

Months:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
School recruitment & registration of asthmatics										X		X									X			X
Intervention delivery										X		X									X			X
Follow-up 1										X		X									X			X
Follow-up 2										X		X									X			X
Follow-up 3										X		X									X			X
Analysis										X		X									X			X
Writing up and dissemination										X		X									X			X

X Key milestones

The first key milestone is at the end of month 10: end of interventions in trial schools

The second milestone is at the end of month 21: end of data collection

X Deliverable

Deliverable end of month 12: intermediate report to the funder

Deliverable month 24: final report to the funder

12. Statistical Analysis and Study Power

The primary outcome measure used for the power calculation for this study is ACT score, as this is a continuous outcome and is therefore more sensitive to differences in asthma control. A power calculation will be used based on 80% power and a significance level of 5% to test a 3 point difference in ACT scores. This 3 point difference is chosen as this is the minimal important

difference. The standard deviation (SD) that is used in the power calculation (SD = 4.3) comes from our earlier school-based asthma study.

The power calculation is adjusted to allow for Intracluster correlation (ICC), as is required for cluster randomised trials. An ICC of 0.07 was chosen, taken from a study of asthmatics where a questionnaire was the outcome measure, but the clusters to be randomised were GP surgeries rather than schools. This means that the ICC is likely to be a conservative estimate for our study, as children in different schools are likely to be less heterogeneous than patients in different GP surgeries.

The findings from the intervention will be analysed quantitatively, using SPSS. Statistical analyses will include descriptive statistics, Mann-Whitney U tests, and chi-squared analysis.

13. Sponsorship and Indemnity

This trial will be sponsored by Queen Mary University of London. The contact details for the sponsor can be found at the beginning of the protocol. The Joint Research and Management Office (JRMO) will arrange suitable indemnity for negligent harm arising as a result of participation in this study to be in place.

14. Dissemination

Regular meetings will be held with key Patient and Public Involvement (PPI) stakeholder groups to plan key messages from our research. This will include the lay research advisory panel at the NIHR CLAHRC North Thames, as well as teachers, teenagers and parents.

Established channels of social media will be used to disseminate the findings of the intervention. This will include the established twitter account for the project (@SchoolsAsthma) to reach key organisations, and tweet important messages related to this work.

We will also work closely with our established partners, such as Healthy London Partnership, AUKCAR, and the Asthma UK knowledge exchange team to disseminate the findings to the media and relevant stakeholders, and to continue developing this research.

The findings of the intervention will be submitted at national and international conferences, attended by clinicians within the field. We will also look to present our findings at local authority

health and well-being boards. The findings will also be submitted to a peer-reviewed journal. If successful, a grant application will be submitted to the NIHR to support the implementation of the intervention across the UK.

Elements of this work is also presented at events organised by companies associated with our research. This has previously included the QMUL Festival of Communities, Barts Health NHS Trust Paediatric Asthma Study Day, and Barts and QMUL Science Festival. Attendees at these events have previously included school children and teachers, healthcare professionals, and the general public.

Finally, the project's research approach will be documented through a short documentary film, which will be available on the research team's website.