Pilot Study Assessing a Communication Intervention on Absences in School Age Children with Asthma (PLANES): Study protocol for pragmatic cluster-randomised pilot study

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Background

Asthma is a long-term inflammatory condition that affects the airways in both children and adults, characterised by fluctuating respiratory symptoms and variable airflow limitation. Although intensity fluctuates, the condition usually persists through life (Papi *et al.*, 2018). In the UK, approximately 7.2 million people, around 8% of the population, have asthma, including 1.1 million children receiving treatment (*Asthma + Lung UK*, 2024). Asthma remains to be one of the leading causes of emergency hospital admissions among children and young people (Keeble and Kossarova, 2017). A systematic review by Merghani et al. reported that asthma places a considerable burden on school attendance, affecting 29% of students and leading to an average of 4.15 missed school days each year. Children with asthma are nearly three times as likely to miss school compared to their peers without asthma (Merghani *et al.*, 2025). These absences were shown to impair learning, social engagement, long-term academic outcomes, and contribute to family stress and work disruption (Merghani *et al.*, 2025).

Asthma exacerbations and school absences follow a seasonal pattern, with a sharp increase in the Autumn after school resumes (Johnston *et al.*, 2006). Medical visits for children with asthma rise markedly between September and December, nearly doubling compared with peers without asthma (Julious *et al.*, 2011). Among children aged 5 to 15 years, hospital admissions and emergency visits remain relatively stable during the first half of the year but fall during summer months, likely due to reduced exposure to triggers, inconsistent preventer use, fewer infections, and increased outdoor activity (Fleming *et al.*, 2000; Johnston *et al.*, 2006). This seasonal rise in unplanned medical contacts corresponds with lower adherence to preventer medication and reduced prescription uptake during the summer holiday period (Julious *et al.*, 2011).

Julious et al. (2018) conducted a cluster randomised controlled trial (cRCT) called PLEASANT (Preventing and Lessening Exacerbations of Asthma in School-age children Associated with a New Term) across 142 general practices in England and Wales. The intervention involved sending a pre-summer holiday reminder letter to parents or carers of school-aged children with asthma, emphasising the importance of continuing preventative asthma medication during the summer period. The intervention was associated with a 30% rise in prescription collection during August and a subsequent reduction in unscheduled healthcare use following the return to school between September and December. Although the observed effects were small, the intervention was economically favourable, resulting in an estimated saving of £36.07 per patient over a 12-month period (Fig. 1) (Julious *et al.*, 2018).

Schools offer an accessible and structured setting for recruiting children, implementing public health interventions, and tracking their effects overtime (Goesling, 2019). Using principles from behavioural science, invitation letters can enhance participation in health programs (Sallis *et al.*, 2016). Letters informed by behavioural insights have proven successful in promoting parents' action. For example, when an enhanced National Child Measurement Programme (NCMP) letter was sent to parents of children with above-average body mass index (BMI), those parents were more likely to register their children in weight management programmes (Sallis *et al.*, 2019). However, such approaches have rarely been applied to chronic conditions like asthma, despite its prevalence and the burden of asthma related school absence (Gouia *et*

al., 2024; Merghani *et al.*, 2025). Therefore, this pilot cRCT will assess the feasibility and acceptability of a school-based communication intervention aimed at improving medication adherence and reducing asthma related school absences.



Fig. 1 Unscheduled medical contacts and prescriptions uptake over time. (Julious *et al.*, 2018)

Rationale

The PLEASANT trial found that sending reminder letters from general practices before the summer holidays reduced unscheduled medical visits and improved medication uptake. However, this approach has not yet been tested in school settings, where seasonal peaks in asthma morbidity at the start of the academic year are associated with increased asthma-related school absences.

Research question

This project aims to answer the following research question:

"Is it feasible to undertake a pilot pragmatic cluster randomised controlled trial in schools to evaluate whether sending a reminder communication to parents/carers of school aged children aged 5-16 years with asthma can help reduce asthma-related school absences?"

Primary research aim

The primary aim of this project is to assess the feasibility of conducting a pragmatic cRCT in a school setting and to explore whether school-based communication with the parents or caregivers of children with asthma can reduce asthma-related school absences. This aim will be accomplished through the following objectives:

1. To design the intervention in consultation with patient and public involvement (PPI) and implement it within the intervention group before and during the 2026 school summer holidays;
2. To assess the feasibility of undertaking a school-based intervention within a pragmatic cluster-randomised controlled trial;
3. To obtain preliminary data on school recruitment, retention, and follow-up, including pupils with asthma;
4. To make a preliminary assessment of school attendance using routinely collected school attendance data for pupils with asthma;
5. To make a preliminary assessment of school attendance using routinely collected school attendance data for pupils without asthma;
6. To obtain data to inform the design of a definitive trial, including estimates of the intraclass correlation coefficient, standard deviations, response rates, and data completion rates.

Children with asthma are twice as likely to see their general practitioner (GP) after the return back to school (Julious *et al.*, 2011). The expectation is that children with asthma will have more school absences than children without asthma. The estimate of attendance differences between children with and without asthma will give an estimate of the maximum effect that could be observed in a definitive trial.

Methods

Study design

PLANES will be a pragmatic pilot cRCT. A total of 16 primary and secondary schools will be recruited into the trial with an allocation ratio of 1:1, 8 schools in the intervention group and 8 in the control group (Fig. 2). It will be stratified by type of school: primary or secondary. A cluster design ensures operational feasibility while minimising the risk of cross-group contamination. Data will be collected over a six-months period after the implementation of the intervention.

Designing the intervention

The intervention was informed by the COM-B model, which proposes that behaviour is influenced by an individual's capability, opportunity, and motivation (Michie, van Stralen and West, 2011).

A cross-sectional survey was conducted among school-aged children with asthma to identify barriers to regular use of prescribed preventer inhalers (the target behaviour), which were mapped to COM-B subcomponents. These barriers were translated into behavioural targets.

In consultation with my supervisor [RW] survey findings were analysed to examine associations between asthma medication adherence and the capability, opportunity, and motivation constructs. Identified behavioural barriers and facilitators were subsequently translated into behavioural objectives, which informed both the content and design of the intervention. Accordingly, the intervention was designed to target reflective and automatic motivation through reminder-based and persuasive strategies.

The intervention

Survey findings indicated that motivation was the primary factor influencing adherence to asthma medication. Mainly, automatic motivation, such as habits and routines, appeared to play an important role. Based on this finding, the intervention was designed to target this motivational component using reminder and persuasive communication strategies.

The intervention consists of a brief reminder communication delivered by schools to parents or carers of children with asthma before and during the summer holidays in 2026. The intervention will include an initial reminder letter sent approximately 1-2 weeks before the start of the summer holidays, followed by two reminder prompts during the summer holiday period, sent approximately two weeks apart. These follow-up prompts may be delivered through SMS, WhatsApp, email, or the school communication app, depending on the usual communication methods used by the participating school.

The reminder messages aimed to advise parents and carers to ensure their child continues to use their prescribed asthma medication during the summer holidays, a period when daily routines may change and adherence may decline. The aim of the intervention is to support continued asthma medication use during the holiday period, reduce the risk of asthma exacerbations, and promote a smoother return to school in September.

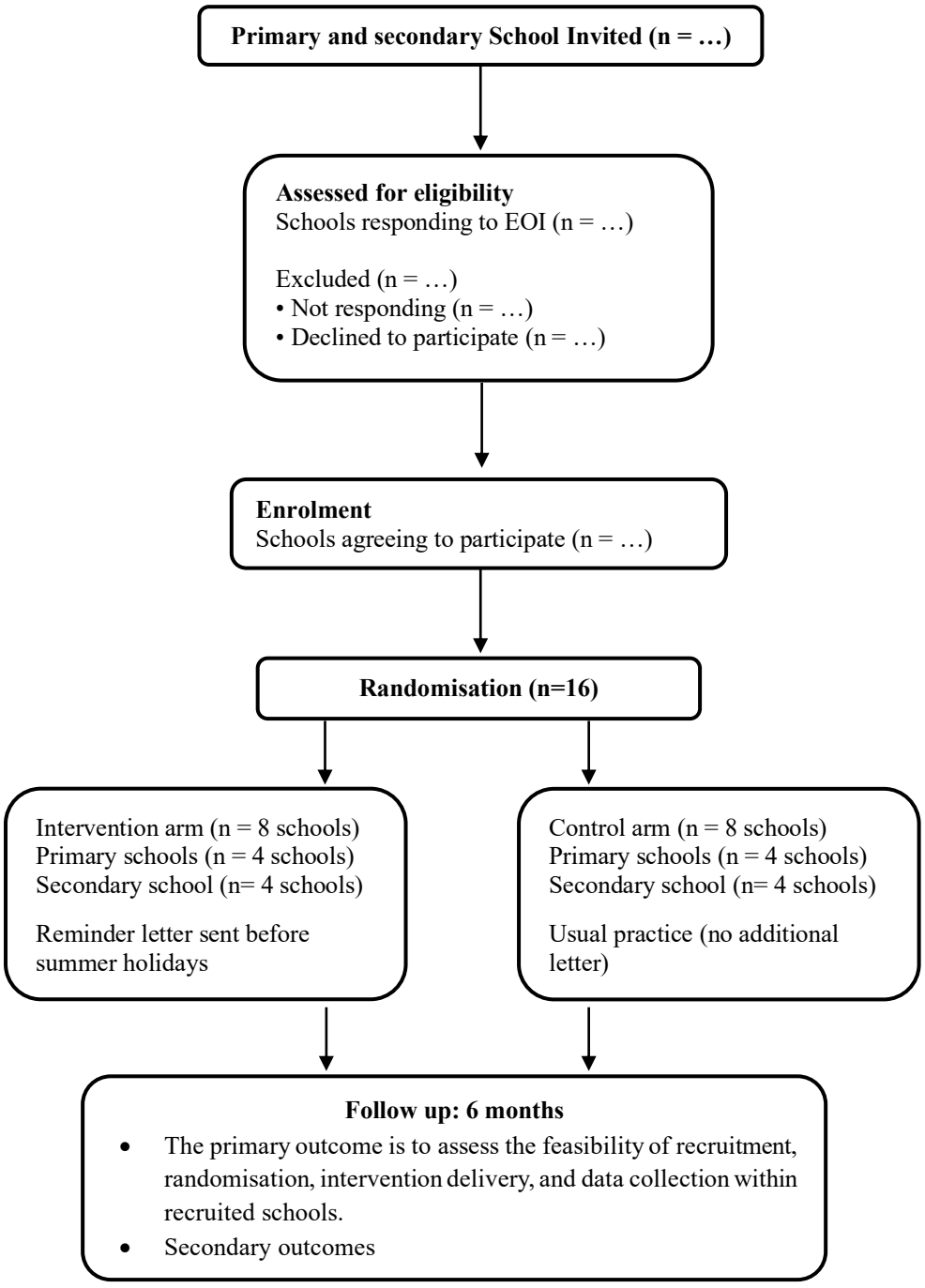


Fig. 2: Study flow summary

Patient and public involvement (PPI)

Patient and Public Involvement (PPI) is embedded within the PLANES study. Children with asthma and their parents have joined a PPI panel and will continue to contribute to the design and delivery of the intervention. PPI members were initially recruited through Dr P. Oliver's General Practice (GP), where they were introduced to the project and its aims in January 2025.

A further PPI consultation was organised in February 2026 in collaboration with the Centre for Applied Respiratory Research, Innovation and Impact (CARRii), during which children with

asthma and their parents participated in an online session to inform refinement and finalisation of the intervention design. Participants agreed that changes in routine during the summer holidays make it more difficult to remember to use preventer medication, and that reminder communications would be helpful. They recommended that an initial letter should be sent directly to parents before the start of the summer holidays, followed by fortnightly prompts delivered via SMS, WhatsApp, or the school app to encourage continued use of the preventer medication throughout the summer break. Participants also suggested that reminder messages sent via SMS should be short and simple to improve readability. Older children noted that they often receive school communications through SMS and WhatsApp. In addition, a parent of a child with asthma was agreed to join the Trial Steering Committee (TSC) to provide ongoing oversight and input. All Children attending both PPI events were offered a £30 gift voucher in recognition of their time and contribution.

School level outcome measures

1. The total number of schools approached, including those that responded to expressions of interest (EOIs) and those that formally agreed to participate via email.
2. The number of schools successfully recruited within a two-month period, defined by the receipt of completed expressions of interest submitted by email, and number of schools subsequently randomised to the intervention or control group.
3. The proportion of participating schools that remained engaged and complied with the study protocol throughout the intervention period.
4. The quality of data collection, assessed by the number of schools submitting end-of-study data and the proportion of submitted data that was complete.
5. The number of children with asthma per school who are eligible for the trial.

Children level outcome measures

1. The proportion of children with asthma experiencing ≥1 school absence in September 2026 and in September-December 2026.
2. The mean number of school days missed per child with asthma in September 2026 and in September-December 2026.
3. Time to first school absence, measured from 1 September 2026, among children with asthma.
4. The proportion of children without asthma experiencing ≥1 school absence in September 2026 and in September-December 2026.
5. The mean number of school days missed per child without asthma in September 2026 and in September–December 2026.
6. Time to first school absence, measured from 1 September 2026, among children without asthma.
7. The total number of school absence days per participating school in September 2026 and in September-December 2026.

Equivalent measures will be calculated for September 2025 and September-December 2025 as baseline measures.

Study settings and site recruitment

The trial will be conducted within primary and secondary schools (clusters) in England, with an initial focus on Sheffield and South Yorkshire. Schools will be recruited through an Expression of Interest (EOI) process, which will be distributed in the first instance to all eligible primary and secondary schools across Sheffield and South Yorkshire. We aim to recruit 16 schools over a two-month period (May 2026 to June 2026). We will seek to recruit schools from a range of socioeconomic backgrounds, where feasible, to enhance the representativeness of the sample.

If recruitment targets are not achieved within Sheffield and South Yorkshire, it will be extended to additional regions across England. Participating schools will receive financial compensation in recognition of the time and administrative effort required to take part. Recruitment will follow the steps outlined below:

1. Ethical approval will be obtained from the School of Medicine and Population Health Research Ethics Committee prior to the commencement of any recruitment activities.
2. Eligible schools will be identified by compiling a list of primary and secondary schools using publicly available information from local authority websites.
3. The EOI and information sheet will be distributed by email to headteachers, accompanied by a covering letter outlining the purpose and the importance of school participation in the study.
4. Schools interested in participating will be asked to complete and return the EOI form.
5. Schools may be invited to attend an optional online information webinar within one week of EOI distribution to learn more about the PLANES study and to ask questions prior to agreeing to participate.
6. Follow-up contact will be undertaken approximately one week after EOI distribution, via email, telephone, or school visits, to confirm receipt, address any queries, and confirm which schools agree to participate.
7. If schools that submits an EOI is part of an academy chain, we will approach other schools within the same chain or contact the academy trust to support recruitment of additional schools.
8. Will approach schools through known informal contacts e.g. members or trial steering committee.
9. We will contact academy trust administrators to facilitate their schools' participation by sharing study information and inviting schools within the trust to express interest in participation.
10. If more than 16 schools' express interest, the first 16 schools that agree to participate will be included in the study. Any additional schools will be placed on a reserve list and may be invited if a school withdraws before randomisation. If needed, schools will be selected using a computer-generated random method.

Randomisation
Following confirmation of school's participation from headteachers or designee. Schools will be randomly allocated in a 1:1 ratio, with eight schools assigned to the intervention group and eight schools to the control group. The randomisation will be generated using a computer-based random number generator. Schools will be informed of their allocation only after randomisation has been completed. All participating schools will contribute to data collection in this study.

Schools allocated to the intervention group will send a reminder communication to parents and carers of children with asthma before and during the summer holidays 2026, whereas schools allocated to the control group will continue with usual practice and will not send any additional asthma-related communication. As the intervention is implemented at the school level, all parents/carers and pupils in participating schools will be informed that their school is taking part in health-related research study. They will also be informed that fully anonymised attendance data from all pupils in participating schools will be extracted by school staff and used for research purposes. This information will be provided before the study starts via usual school communication method such as email, so that families can make an informed decision about the use of their data before data collection.

Population
The intervention will target children and young people aged 5 (before 1 July 2026) to 16 years who attend school and have a diagnosis of asthma. The primary analysis will focus on pupils enrolled during both study periods. Attendance data will be collected for pupils enrolled in participating schools during the baseline period (September-December 2025) and the follow-up period (September-December 2026). Pupils who recently join the school in September 2025 (e.g., reception and Year 7) will be excluded from baseline-follow-up comparisons.

School inclusion criteria
Eligible schools will be primary or secondary schools in England educating children aged 5 to16 years and agree to take part in the trial. Schools must be able to identify pupils with asthma, send the reminder communication if allocated to the intervention group, and provide anonymised attendance register data for the study periods: September-December 2025 (Baseline) and September-December 2026 (Follow-up).

School exclusion criteria
Schools will be excluded if they do not meet the inclusion criteria or decline to participate in the trial. Pupils whose parents/carers have opted out or withdrawn before data transfer will also be excluded from the dataset.

Data collection
All collected data in this study are fully anonymised. No names, dates of birth, addresses, or any identifiable information will be collected. Each pupil will be assigned to an anonymised ID, and the Unique Pupil Number (UPN) will not be transferred to the research team.

Schools will be requested to extract and submit attendance data for all pupils, with and without asthma, in each class/form. Data will be submitted in a standard electronic format (e.g., Excel or CSV). Data collection will cover two periods starting at the beginning of the academic year: September-December 2025 (baseline) and September-December 2026 (follow-up). Data are expected to be received from participating schools by January 2027. Schools will exclude records of pupils whose parents/carers have opted out or withdrawn prior to data transfer. Once data have been anonymised and submitted, individual records cannot be identified for removal.

Statistics

Sample size

A total of 16 schools stratified by type of school will be included in this study, with eight allocated to the intervention arm and eight to the control arm. Recruitment will be structured to ensure equal representation of primary and secondary schools (eight of each). As this is a pilot pragmatic cluster randomised controlled trial, the study is not powered to detect statistically significant differences between trial arms. The sample size has been chosen to assess the feasibility of recruitment, randomisation, intervention delivery, and data collection, and to provide preliminary estimates to inform the design of a future definitive trial (Lewis and Julious, 2021).

The anticipation is that there will be circa 30 children with asthma in each primary school and 100 in each secondary school. This is also an outcome for the study due to uncertainty.

Data analysis

This research is designed as a pragmatic pilot cRCT and is not powered to detect statistically significant differences between trial arms. Analyses will be primarily descriptive and exploratory, with the main purpose of assessing feasibility and estimating parameters to inform the design of a future definitive trial. Study findings will be reported in accordance with the CONSORT extension for pilot and feasibility trials.

The cluster analyses will focus on feasibility outcomes, including school recruitment and retention, adherence to allocated intervention procedures, and the completeness of collected data. These outcomes will be summarised descriptively at the school level and reported by trial arm. The number and proportion of schools contributing outcome data will be presented.

The analyses for children with asthma will explore attendance related outcomes comparing schools allocated to the intervention with schools allocated to the control group (usual practice). This will include the proportion of children with asthma experiencing at least one school absence, the mean number of school days missed per child, and time to first school absence.

Outcomes will be summarised by trial arm and presented with 95% confidence intervals, accounting for clustering where appropriate.

The comparison of school absenteeism between child with and without asthma will be analysed similarly but will be stratified by intervention.

All analyses will follow the intention-to-treat principle at the cluster (school) level, with schools analysed according to their allocated group regardless of intervention delivery.

Full details of the statistical analysis will be described in the statistical analysis plan.

Analysis will be undertaken in IBM SPSS Statistics.

Ethical Consideration

Ethical approval will be obtained from the School of Medicine and Population Health Ethics Committee. In line with Recommendation 3 of the Ottawa Statement on the Ethical Design and Conduct of Cluster Randomised Trials, pupils and their parents/carers are considered research participants because they are the intended recipients of the reminder intervention or are included in data collection. In line with Recommendation 6, seeking individual written consent will not be feasible because this may alter participants' behaviour, and this is a low-risk study (Weijer *et al.*, 2012). Therefore, an alteration of consent requirements is needed. An opt-out system will be used to avoid contamination of the study design.

Parents/carers will be informed about the study through the school's usual communication method before the study starts. This notification will explain the study, confirm that only fully anonymised attendance data will be collected by school staff and used for research purposes, and provide a clear mechanism for raising safeguarding concerns or opting out. Parents/carers will have the option to opt out within two weeks of receiving the notification. They may also withdraw at any point before data collection takes place. If an opt-out or withdrawal request is received after the study has commenced but before data transfer, no data relating to that pupil will be included. Once data have been fully anonymised and submitted, individual records cannot be identified for removal. Attendance data will be submitted to the research team in January 2027.

Study governance

An independent TSC is established to provide oversight of the study and to ensure it is conducted in accordance with appropriate scientific, ethical, and governance standards. The committee consist of an independent chair, a statistician, a teacher, paediatrician, and a parent representative, and the principal investigator. The role of the TSC is to provide independent advice to the research team, monitor study progress, protocol adherence, oversee the delivery and fidelity of the intervention, and to ensure that the study is conducted in the line with ethical approval.

Acceptability of the Intervention

After submitting the register data, school staff will be invited to complete a brief online questionnaire assessing the acceptability of the study procedures. Staff in intervention schools will be asked additional questions about delivering the reminder communication.

The questionnaire is informed by the Theoretical Framework of Acceptability (TFA) (Sekhon, Cartwright and Francis, 2022). It will be administered electronically via Qualtrics or another university-approved platform. Responses will be analysed to inform feasibility and fidelity of the intervention. Heateacher or school representative will be asked to provide informed consent before completing the questionnaire.

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