Pharmacy Trial Program – Asthma and Rhinitis Control (PTP-ARC): Statistical Analysis Plan

Version 1.1 (final)

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STATISTICAL ANALYSIS PLAN APPROVAL SHEET

Study: Getting asthma under control using the skills of the community pharmacist

Principal Authors of Analysis Plan

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The undersigned have reviewed this plan and find it to be consistent with the requirements of the protocol as it applies to their respective areas. The principal authors also find this plan to be in compliant with ICH-E9 and The George Institute's SOP ST-SOP-04

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1 Study design

1.1 Overview

The Pharmacy Trial Program (PTP) is a component of the current Sixth Community Pharmacy Agreement (6CPA). The 6CPA is an Agreement between the Commonwealth of Australia (as represented by the Australian Government Department of Health) and the Pharmacy Guild of Australia which includes an investment of \$50 million for the PTP to trial new expanded Community Pharmacy Programmes. It seeks to improve clinical outcomes for consumers and/or extend the role of pharmacists in the delivery of primary health care services through community pharmacy.

The Asthma and Rhinitis Control (PTP-ARC) is one of several Australian Government funded trials being conducted under the PTP. It aims to address the need to improve clinical outcomes for the population at risk of uncontrolled asthma, by extending the role of pharmacists in the delivery of primary health care services through a community pharmacy. This intervention targets three key factors associated with uncontrolled asthma: (i) poor adherence, characterised by underuse of preventer medication and/or overuse of reliever medication, (ii) suboptimal inhaler technique and/or (iii) uncontrolled allergic rhinitis.

Once finalised, the outcomes of all PTP trials will be evaluated by an independent health technology assessment committee (such as the Medical Services Advisory Committee) to inform decisions about any broader roll-out.

Research Question: To compare the effectiveness (increase in proportion of patients with controlled asthma) and cost effectiveness of a pharmacist-delivered asthma service comprising consultations with the pharmacist over a 12-month period for people with uncontrolled asthma (group A) with a “low-level” pharmacy intervention comprising identification of uncontrolled asthma with referral to the GP (group B).

Hypothesis: The primary hypothesis is that a pharmacist-delivered asthma service comprising four consultations with the pharmacist over a 12-month period for people with uncontrolled asthma will be more effective and cost effective than a “low level” pharmacy intervention comprising identification of uncontrolled asthma with referral to the GP.

1.2 Design

A clustered randomised controlled design trial (RCT) will be implemented. The cluster will be the community pharmacy and the unit of analysis the patient. It will comprise two groups and will run for approximately 1.5 years.

Group A: Intervention - Pharmacist asthma service - three private consultations with the patient over a period of 12 months (at baseline, one month and 12 months), with a six-month telephone check-up mid-program. The consultation will focus on addressing three key factors associated with uncontrolled asthma: poor adherence characterised by underuse of preventer medication and/or over use of reliever medication, suboptimal inhaler technique and uncontrolled allergic rhinitis if applicable. The service will be delivered in 40 pharmacies from NSW, WA or TAS, each delivering the service to 7 patients.

Group B: Low intervention - Pharmacy screening for uncontrolled asthma and referral to GP. 40 pharmacies from NSW, WA or TAS. This includes two phone calls with patients at Month 1 and Month 12.

Sample size: Assuming that no more than 30% of patients from Group B will have controlled asthma by 12 months and around 50% with controlled asthma in Group A (a 20% absolute increase between Group B and Group A), a total of 68 pharmacies (34 pharmacies each in Group A versus Group B) each recruiting a minimum of 5 patients will provide 90% power to test a difference in proportions with an intra-cluster correlation of 0.10. Allowing for a 20% patient dropout and a 15% pharmacy dropout the requisite sample would consist of 80 pharmacies (40 each in Group A versus Group B), with seven patients per cluster, giving a total of 280 per group (560 in total). Stratified selection of pharmacies will occur to represent the different levels of rural and remoteness in NSW, WA and Tas. Pairs of pharmacies will be matched on size and rurality and randomly allocated to intervention or control group.

1.3 Eligibility

1.3.1 Site eligibility

To be eligible to participate, a community pharmacist must:

- Be approved to dispense PBS medicines as part of the National Health Scheme defined in Section 90 of the National Health Act 1953 (Cth) (Section 90 pharmacy)
- Have an area of the community pharmacy that is physically separated from the retail trading floor so that the privacy and confidentiality of the patient is protected
- Have a minimum of two pharmacists on duty at times when the service is to be delivered
- Obtain written patient consent in accordance with the Australian Privacy Principles (APP 3, APP 5, APP 6, APP 11 and APP 12)
- Adhere to the appropriate standards, terms and conditions, guidelines and protocols when providing the service
- Agree to recruit a minimum of seven patients, and provide the data required for the evaluation of this trial

1.3.2 Patient eligibility

Inclusion criteria:

- Current diagnosis of asthma (symptoms of asthma plus use of asthma medication in the past 12 months)
- 18 years or older
- ACQ score of 1.5 or over
- Able to communicate with the pharmacist in English
- A regular client of the pharmacy
- Managing their own medication

Exclusion criteria:

- High dependence on medical care
- Unable to manage own medication
- A confirmed diagnosis of COPD
- Terminal illness

1.4 Randomisation and blinding

The trial will use a cluster-randomised design with pharmacies as the unit of randomisation and patients as the unit of analysis. Pharmacies will be randomised by the research manager to pharmacy asthma intervention (Group A) or screening and referral (Group B). Randomisation will be stratified by metro/urban/rural residential areas, matched to the distribution of the Australian population.

1.5 Outcomes

1.5.1 Primary outcome

The proportion of patients who have controlled asthma at 12 months (Groups A and B) as measured by the Asthma Control Questionnaire (ACQ score ≥ 1.5) [1]. In addition, the primary outcome will be compared at one month (Groups A and B).

1.5.2 Secondary outcomes

- **Group A and B:**
 - Mean change in ACQ score between baseline and one month and baseline and 12 months
 - Mean change in asthma-related QOL between baseline and one month and baseline and 12 months
 - Mean change in RCAT score between baseline and one month and baseline and 12 months
 - Change in proportion of patients using preventer therapy over 12 months.

- Change in adherence between baseline and 12 months post-intervention based on Pharmacy Dispensing Data and Full PBS Dispensing Data
- Number of GP presentations for asthma over 12 months
- Cost effectiveness and cost utility over 12 months
- **Group A only:**
 - Change in medication adherence between baseline and 12 months post-intervention based on self-report
 - Mean change in inhaler technique scores between baseline and one month in group A and baseline and 12 months post-intervention
 - Patient and pharmacist satisfaction with the model in intervention arm

1.5.3 Exploratory outcomes

- Proportion of patients with an asthma action plan at 12 months

2 Statistical analysis

2.1 Analysis principles

- Analyses will be conducted on an intention-to-treat (ITT) basis. That is, by analysing all patients according to the group they were randomly allocated to and regardless of protocol adherence.
- All tests are to be two-sided with a nominal level of α set at 5%.
- Subgroup analyses will be carried out irrespective of whether there is a significant intervention effect on the primary outcome.
- No formal adjustments for multiplicity will be applied. However, the outcomes will be categorised by the degree of importance (primary vs. secondary), and only a limited number of subgroup analyses are pre-specified. The results will be interpreted in this context.
- Analyses will be conducted primarily using SAS software (version 9.3 or above).
- A blind review will be conducted to help finalise some data definitions and assumptions. We anticipate that the blind review will be used to confirm the following aspects:
 - Baseline categorical variables with small categories may be aggregated to avoid model instability and convergence issues in adjusted analyses (relevant to Sections 2.5.2 and 2.7.2).
 - Algorithms to define adherence based on medication history and PBS data (see Section 2.2.2).
 - The definition of time windows to attribute medication changes to the relevant visit (see Section 2.2.3).

2.2 Data definitions

2.2.1 Dataset analysed

Due to the cluster design, the group allocation for a patient will be determined by the pharmacy they were enrolled in. The ITT analysis set will be used to assess all outcomes.

2.2.2 Adherence definition

Adherence scores will be based on multiple sources including:

1. **Full PBS Dispensing Data** (Group A and B) – Primary adherence indicator
Complete dispensing history for all patients who provided consent for PBS linkage, including data from all pharmacies where they had medications dispensed. It includes both below co-payment medicines and above co-payments medicines (excluding items dispensed as 'Private' or those not on the PBS List). This will include 24 months of data (12 months before baseline and the full 12 months duration of the trial).

2. **Pharmacy Dispensing Data** (Group A and B).

Pharmacy specific data manually entered by the research team including 24 months of data (12 months before baseline and the full 12 months duration of the trial).

3. **Self-reported adherence using a visual analog scale (VAS)** (Group A only)

Data collected when participants were asked to self-complete an adherence VAS on an electronic tablet during the intervention. Collected at Baseline, Month 1 and Month 12. (Note: Responses ≤ 0.5 will be coded as missing data and responses > 0.5 coded as 1)

4. **Pharmacist assessment** (Group A only)

Proportion of Days Covered (PDC) will be used to calculate “Global Baseline Adherence” and “Global 12 Month Adherence” Scores from both the Pharmacy Dispensing Data and the PBS Dispensing Data for each participant.

PDC refers to the proportion-of-days-covered by medication dispensed. A PDC of 80% or higher has been defined as representing adherence and lower than 80% as non-adherence. The formula for calculating PDC appears below:

$$\text{PDC} = \left(\frac{\text{Number of days in period "covered"}}{\text{Number of days in period}} \right) \times 100\%$$

In case no instructions for medication administration appear in the medication record, a standard dosage administration to calculate the number of days supplied for each medication dispensed is used. For both data sets (Pharmacy Dispensing Data and Full PBS Dispensing Data), PDC will be calculated for each preventer medicine at baseline and at 12 months. Each PDC calculation will use data from a 12-month period. For the purpose of the analysis, to be classified as Adherent on the Global Adherence Score, a respondent should have a PDC $>80\%$ [2]. Global Adherence Scores will be dichotomised (adherent or non-adherent). Global Adherence Scores from the Pharmacy Dispensing Data will be used for the Baseline Paper as Full PBS Data will not be available until later in the project.

2.2.3 Visit windows

For the primary analyses, including the analysis of the primary outcome at Month 12, we will analyse all data collected at the corresponding visit, regardless of the exact timing of the visit. For example, if a month 1 visit was conducted 60 days after baseline (instead of 30 days ideally), we will still analyse data collected at that visit as month 1 data.

Sensitivity analyses only including data from visits collected within specific time windows will be conducted to assess the robustness of the results. Data from a visit falling outside of the corresponding window will be excluded from sensitivity analyses; however, data from a visit falling inside the window will be included. As a result, an individual participant will only be

completely excluded from the sensitivity analyses if all his/her visits fall outside of the corresponding windows.

For the purpose of the sensitivity analyses, visit windows are tentatively* defined as follows:

- Month 1: Day 20 and Day 50 (30-day window)
- Month 6: Day 160 and Day 220 (60-day window)
- Month 12: Day 330 and Day 420 (90-day window)

** These windows are subject to adjustment following a review of the distribution of “days from randomisation” at each visit once the data collection is (near) complete.*

2.3 Trial profile

The flow of patients through the study will be displayed in a CONSORT diagram.

2.4 Cluster characteristics and baseline comparisons

Description of the cluster (pharmacy) characteristics will be presented by group. These will include state and remoteness (phARIA code) summarised by frequencies and percentages.

2.5 Patients characteristics and baseline comparisons

2.5.1 Descriptive analyses

Description of the baseline characteristics will be presented by treatment group (A and B) and overall as outlined in Appendix (Table 1). Discrete variables will be summarised by frequencies and percentages. Percentages will be calculated according to the number of patients in whom data are available. Continuous variables will be summarised by using mean and SD, and median and interquartile range (Q1-Q3). No adjustment for clustering will be applied to the summary statistics themselves; however, given the clustered randomisation, we will compute p-values to assess potential baseline imbalances while adjusting for clustering [3]. For continuous characteristics, this will be done using a linear mixed model including a fixed effect of the intervention and a random effect of the cluster. For categorical characteristics, this will be done using a logistic mixed model. Baseline measures for all patients will be tabulated with at least the following variables outlined below:

Baseline variables common to the control and intervention group:

- Location of pharmacy
- ACQ Score and responses to each ACQ questions (including reliever use)
- SF12 Score
- AQOL Score and responses to each AQOL question
- Patient Demographics (Age, Gender, Work Status, Education Status)

- Asthma History (age of onset, Accident and Emergency Visits and Hospitalisations in the last 12 months, Lung function tests prevalence and smoking status).
- Adherence derived from pharmacy dispensing records and PBS data (see Section 2.2.2)
- Allergic Rhinitis Status (for those with allergic rhinitis)
- RCAT Score and responses to each question (for those with allergic rhinitis)

Baseline variables collected in the intervention group only:

- Reliever use
- Adherence Status based on self-report (VAS) and pharmacist assessment
- Asthma Knowledge
- Medication Knowledge
- Inhaler technique
- Allergic rhinitis symptoms and medications
- Co-Morbidities

2.5.2 Factors associated with worse asthma control

Using baseline data from both groups combined, we will conduct analyses to identify factors associated with worse asthma control at baseline. The outcome will be the asthma control score analysed as a continuous dependent variable. Potential covariates/independent variables will include the following variables:

- Patient Demographics: age, gender, work status, education status, concession card and rurality (pharmacy remoteness – 3 categories).
- Asthma History: age of onset, number of accident or emergency visits in the past 12 months, number of hospitalisations in the last 12 months, lung function test history (yes/no), smoking status.
- History of allergic rhinitis (yes/no).
- Baseline adherence (yes/no) to asthma medications derived from Pharmacy Dispensing Data (see Section 2.2.22.2.2).
- Use of oral corticosteroid in 12 months prior to the study (yes/no).

All variables will then be included in multivariable linear regression model without further selection. Only in case of high collinearity (a correlation coefficient > 0.8) between two covariates will we select the variable that had the smallest univariate p-value. The multivariable regression model will consist in a linear regression model with the asthma control score as the outcome and including a random pharmacy effect to adjust for clustering. Results will be reported as adjusted means and 95% confidence intervals.

2.6 Outcomes collected only in the intervention group

A range of outcomes are measured only in the Intervention group (A). These will be summarised at each relevant visit using standard measures of central tendency and variability and, for outcomes collected at all 3 timepoints (baseline, month 1 and month 12), displayed using bar charts (categorical outcomes) or mean plots (continuous outcomes) per visit.

These outcomes (with corresponding variable names included between parentheses) include:

- Adherence to medications
 - Self-reported adherence (BL_VAS1_Adh)
 - Adherence as reported by pharmacist (BL_Adherent_Non -Yes/no)
 - Reliever use (BL_Reliever_7, BL_Reliever_Average, BL_Reliever_Appropriate)
 - Proportion of patients that required assistance in the following:
 - Addressing concerns about asthma (BL_Concerned, BL_Conc_Medication related concerns - BL_Conc__Other)
 - Revision of Asthma Knowledge (BL_Knowledge)
 - Revision of Medication Understanding (BL_Understand)
 - Eliciting and addressing factors that bothered the patient about their asthma (BL_Bothered, BL_Both_Adverse effects- BL_Bother_Other)
 - Provision of tools to help patients remember to use and collect medications (BL_Remember, BL_Repeats)
 - Changes made to medications over the duration of the trial.
 - Steps taken to improve adherence (BL_Adh_Actions)
- Inhaler technique
 - Proportion of inhaler technique demonstrations required
 - Proportion of patients leaving each session with technique mastered
- Hay fever medications
 - Changes in treatment
 - Outcome of allergic rhinitis treatment recommendations

Measures of intervention delivery such as time taken, GP referrals made, GP visits made, patient retention and patient satisfaction will be analysed separately and reported in a subsequent manuscript.

2.7 Analysis of the primary outcome

2.7.1 Main analysis

The primary endpoint is a binary variable indicating whether asthma is controlled at 12 months. Controlled asthma is defined as an ACQ score < 1.5. This will be analysed using repeated-measure mixed logistic regression including both the Month 1 and Month 12 values as

dependent variables. Fixed effects will include the random group allocation (A or B), the visit (Month 1 or Month 12), the interaction between the group allocation and the visit and the baseline value of the ACQ score as a continuous variable. A random intercept per cluster will be included to account for intra-cluster correlations.

The main effect of the intervention will be estimated as the odds-ratio for Group A vs Group B at Month 12 together with its 95% confidence interval. From the logistic regression model we will also derive the relative risk and risk difference [4]. All estimates will be computed at the overall mean of the baseline ACQ score. The effect of the intervention at Month 1 will be estimated from the same model, using the same approach.

2.7.2 Adjusted analyses

The logistic regression model described in Section 2.7.1 will be re-run after adjustment for baseline covariates. The following covariates will be considered for inclusion:

- Patient age
- Gender
- Education status
- Work status
- Age since diagnosis
- Smoking status
- Baseline adherence (derived from PBS data)
- History of hay fever
- Pharmacy state
- Pharmacy remoteness

The above covariates with a univariate p-value smaller than 0.20 will be considered for inclusion. The univariate test will consist of a repeated-measure mixed logistic regression with the ACQ score at months 1 and 12 as the outcome, the baseline covariate of interest as a fixed effect and the cluster as a random effect. In case of collinearity between two covariates (two variables with a correlation coefficient below -0.8 or above 0.80) only the variable with the strongest (i.e. smallest) univariate p-value will be included in the adjusted model. In case of convergence issues, pharmacy-level covariates (state and remoteness) will be removed. Additional covariates not listed above may be included in case of imbalanced baseline characteristics as indicated by significant p-values ($p < 0.05$).

2.7.3 Subgroup analyses

The following subgroup analyses will be carried out for the primary outcome only:

- Age (<56, 56 years and above)
- Sex

- State (of pharmacy)
- Remoteness (of pharmacy)

The analysis for each subgroup analysis will be performed by adding the subgroup variable as well as its interaction with the intervention as fixed effects to the logistic regression model used for the primary analysis (see Section 2.7.1). Within each subgroup, summary measures will include raw counts and percentages within each treatment arm, as well as the OR for treatment effect with 95%CI. The results will be displayed on a forest plot including the P value for heterogeneity corresponding to the interaction term between the intervention and the subgroup variable.

2.7.4 Treatment of missing data

The primary analysis will use all available data with no imputation. In addition, if the ACQ score at 12 months (the primary endpoint) is missing for more than 10% of enrolled patients, missing data will be imputed using a fully conditional specification (FCS) [5]. The imputation model will include the ACQ score at baseline, 1 month and 12 months, a variable indicating the pharmacy (cluster), a variable indicating the intervention, as well as the following baseline variables: SF12 scores (Mental and Physical), AQOL score, age, sex, work status, education status, age since diagnosis, history of lung function test, smoking status and allergic rhinitis status. Binary variables will be imputed using a logistic model. Other variables will be imputed using either linear regression (for continuous/ordinal variables) or a discriminant function method (for nominal variables). Ten sets of imputed data will be created and analysed using the model described in Section 2.7.1. Estimates of the treatment effect and its standard-errors will be combined to obtain a pooled common OR and 95% CI.

2.8 Analysis of secondary outcomes measured in groups A and B

2.8.1 Binary outcomes

Secondary and exploratory binary outcomes measured at baseline, month 1 and month 12 will be analysed using the same model as the one described in Section 2.7.1. This applies to:

- Presence of an asthma action plan (Month 12 only)
- Appropriate use of preventer therapy, defined as $\geq 80\%$ adherence based on the adherence calculated from Medication History variables (see Section 2.2.2 for detailed definitions of adherence measures)
- Appropriate use of reliever therapy, defined at $< 3-4$ puffs per day vs $\geq 3-4$ puffs per day (Question 6 of the ACQ)

No adjusted, subgroup or imputed analysis will be performed on these outcomes.

2.8.2 Continuous scores

Continuous scores measured at baseline, Month 1 and Month 12 (and Month 6 for the ACQ) will be analysed using linear mixed models similar to the model described in Section 2.7.1 but assuming a normal distribution and an identity link function. The effect of the intervention will be presented as the mean difference and associated 95% CI at Month 12 and Month 1. This approach applies to the following outcomes:

- ACQ score
- Asthma-related QOL score
- RCAT score

No adjusted, subgroup or imputed analysis will be performed on these outcomes:

2.9 Individual questions to questionnaires

The individual questions that form the ACQ, QoL and RCAT questionnaires will be described by group at each visit.

2.10 Economic evaluation

A within-trial cost-effectiveness analysis and cost-utility analysis will be conducted from the health care system perspective. The health outcomes used will be the number of individuals with controlled asthma and health-related quality of life (HRQOL) as measured by the SF-12. The SF-12 will be converted into a utility score, known as the SF-6D [6,7] to estimate the quality-adjusted life years (QALYs) accrued over a 12-month period. Costs associated with the pharmacists' consultation time, administratively linked data for individuals' pharmaceutical (PBS) and medical services (MBS), and self-reported ED presentations will be included.

A seemingly unrelated regression (SUR) model will be used to estimate the costs and health outcomes, accounting for the correlation between costs and outcomes in individuals within the same cluster as well as the between cluster levels. Clustering and covariate adjustment will be accounted for as per the main statistical analysis. Incremental cost-effectiveness ratios (ICERs) will be estimated based on the mean incremental effect of pharmacy compared to GP referral on total costs and health outcomes. Non-parametric bootstrapping will be conducted to estimate uncertainty around the ICER and calculate confidence ellipses using the variance-covariance matrix estimated from the SUR.

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4 Appendix: Proposed main tables and figures

Figure 1: Consort flowchart

Table 1: Baseline characteristics

	Control (n=xxx)	Intervention (n=xxx)	All (n=xxx)	P-value ¹
Pharmacy state	N=xxx	N=xxx	N=xxx	
New South Wales	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Tasmania	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Western Australia	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Pharmacy remoteness	N=xxx	N=xxx	N=xxx	
Highly accessible	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Accessible	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Moderately accessible, remote, very remote	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Age (years)	N=xxx	N=xxx	N=xxx	0.xxx
18 to 25, n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
26 to 35, n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
36 to 45, n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
70-<, n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
≥80, n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Sex	N=xxx	N=xxx	N=xxx	0.xxx
Females, n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Males, n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Work situation	N=xxx	N=xxx	N=xxx	0.xxx
Full-time employment, n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	

Part-time or casual employment, n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Home duties, n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Full-time carer, n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Retired/pensioner, n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Other, n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Level of education	N=xxx	N=xxx	N=xxx	0.xxx
No formal education, n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Primary school, n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
High school, n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Tertiary non-university (e.g. TAFE), n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
University, n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Post-graduate, n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Age begin to experience Asthma	N=xxx	N=xxx	N=xxx	0.xxx
0-5 years of age	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
6-15 years of age	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
16-34 years of age	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
35-55 years of age	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
above 55 years	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Ever had a lung function test	N=xxx	N=xxx	N=xxx	0.xxx
No	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Yes	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Last lung function test	N=xxx	N=xxx	N=xxx	0.xxx

In the last 12 months	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
More than 12 months ago	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Active smoker	N=xxx	N=xxx	N=xxx	0.xxx
No	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Yes	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
History of hay fever	N=xxx	N=xxx	N=xxx	0.xxx
No	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Yes	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
RCAT score	N=xxx	N=xxx	N=xxx	0.xxx
mean (SD)	xxx (xxx)	xxx (xxx)	xxx (xxx)	
median (Q1-Q3)	xxx (xx-xx)	xxx (xx-xx)	xxx (xx-xx)	
min - max	xxx - xxx	xxx - xxx	xxx - xxx	
AQOL score	N=xxx	N=xxx	N=xxx	0.xxx
mean (SD)	xxx (xxx)	xxx (xxx)	xxx (xxx)	
median (Q1-Q3)	xxx (xx-xx)	xxx (xx-xx)	xxx (xx-xx)	
min - max	xxx - xxx	xxx - xxx	xxx - xxx	
ACQ score	N=xxx	N=xxx	N=xxx	0.xxx
mean (SD)	xxx (xxx)	xxx (xxx)	xxx (xxx)	
median (Q1-Q3)	xxx (xx-xx)	xxx (xx-xx)	xxx (xx-xx)	
min - max	xxx - xxx	xxx - xxx	xxx - xxx	
SF12 mental health score	N=xxx	N=xxx	N=xxx	0.xxx
mean (SD)	xxx (xxx)	xxx (xxx)	xxx (xxx)	

median (Q1-Q3)	xxx (xx-xx)	xxx (xx-xx)	xxx (xx-xx)	
min - max	xxx - xxx	xxx - xxx	xxx - xxx	
SF12 physical health score	N=xxx	N=xxx	N=xxx	0.xxx
mean (SD)	xxx (xxx)	xxx (xxx)	xxx (xxx)	
median (Q1-Q3)	xxx (xx-xx)	xxx (xx-xx)	xxx (xx-xx)	
min – max	xxx - xxx	xxx - xxx	xxx - xxx	

Note: p-value calculated using a linear mixed model or logistic mixed model with a fixed intervention effect and a random cluster effect.

Table 2: Results of multivariable linear regression for poor asthma control

	Raw estimates ¹		Adjusted estimates ²	
	Mean (95% CI)	P-value	Mean (95% CI)	P-value
Pharmacy state		0.xxx		0.xxx
New South Wales	xx.xx (xx.xx to xx.xx)		xx.xx (xx.xx to xx.xx)	
Tasmania	xx.xx (xx.xx to xx.xx)		xx.xx (xx.xx to xx.xx)	
Western Australia	xx.xx (xx.xx to xx.xx)		xx.xx (xx.xx to xx.xx)	
Pharmacy remoteness		0.xxx		0.xxx
Highly accessible	xx.xx (xx.xx to xx.xx)		xx.xx (xx.xx to xx.xx)	
Accessible	xx.xx (xx.xx to xx.xx)		xx.xx (xx.xx to xx.xx)	
Moderately accessible, remote, very remote	xx.xx (xx.xx to xx.xx)		xx.xx (xx.xx to xx.xx)	
Age (years)		0.xxx		0.xxx
18 to 35, n (%)	xx.xx (xx.xx to xx.xx)		xx.xx (xx.xx to xx.xx)	
36 to 45, n (%)	xx.xx (xx.xx to xx.xx)		xx.xx (xx.xx to xx.xx)	
46 to 55, n (%)	xx.xx (xx.xx to xx.xx)		xx.xx (xx.xx to xx.xx)	
Above 56, n (%)	xx.xx (xx.xx to xx.xx)		xx.xx (xx.xx to xx.xx)	
Sex		0.xxx		0.xxx
Females, n (%)	xx.xx (xx.xx to xx.xx)		xx.xx (xx.xx to xx.xx)	
Males, n (%)	xx.xx (xx.xx to xx.xx)		xx.xx (xx.xx to xx.xx)	
Work situation		0.xxx		0.xxx
Full-time employment, n (%)	xx.xx (xx.xx to xx.xx)		xx.xx (xx.xx to xx.xx)	
Part-time or casual employment, n (%)	xx.xx (xx.xx to xx.xx)		xx.xx (xx.xx to xx.xx)	

Retired/pensioner, n (%)	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
Other ³ , n (%)	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
Level of education	0.xxx	0.xxx
High school or less, n (%)	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
Tertiary non-university (e.g. TAFE), n (%)	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
University and post-graduate, n (%)	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
Concession card	0.xxx	0.xxx
No	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
Yes	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
Age begin to experience Asthma	0.xxx	0.xxx
0-5 years of age	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
6-15 years of age	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
16-34 years of age	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
35-55 years of age	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
above 55 years	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
Ever had a lung function test	0.xxx	0.xxx
No	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
Yes	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
At least 1 accident or emergency visit in the past 12 months	0.xxx	0.xxx
No	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
Yes	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
At least 1 hospitalisation the past 12 months	0.xxx	0.xxx

No	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
Yes	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
Age began to experience Asthma	0.xxx	0.xxx
0-5 years of age	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
6-15 years of age	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
16-34 years of age	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
35-55 years of age	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
above 55 years	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
Active smoker	0.xxx	0.xxx
No	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
Yes	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
History of hay fever	0.xxx	0.xxx
No	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
Yes	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
Baseline adherence to asthma medications	0.xxx	0.xxx
No	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
Yes	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
Use of oral corticosteroids in past 12 months	0.xxx	0.xxx
No	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)
Yes	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)

Note:

- 1) Univariate linear mixed model with a random pharmacy effect.
- 2) Multivariable linear mixed model with a pharmacy cluster effect.
- 3) Work situation – other: includes ‘home duties’, unemployed or seeking work’, ‘full-time carer’ and ‘other’.

Table 3: Baseline comorbidities (Intervention group only)

Symptom or diagnosis	Control (n=xxx)
GORD	xxx (xx.x%)
Sleep related issues	xxx (xx.x%)
Obesity	xxx (xx.x%)
Depression or anxiety	xxx (xx.x%)
Eczema	xxx (xx.x%)

Programming note: denominator should be all those who answered the question “*Patient have symptoms or have a current diagnosis of any of these co-morbidities*”. It should be all 220 patients recruited to Group A.

Table 4: Hay fever (Intervention group only)

	Baseline (N=XXX)	Month 1 (N=XXX)
Any hay fever symptoms	N=xxx	N=xxx
No	xxx xx.x%	xxx xx.x%
Yes	xxx xx.x%	xxx xx.x%
How bothersome are your current nasal symptoms	N=xxx	N=xxx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)
Median (Q1; Q3)	x.x (x.x; x.x)	x.x (x.x; x.x)
min max	xx xx	xx xx
How bothersome are your current eye symptoms	N=xxx	N=xxx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)
Median (Q1; Q3)	x.x (x.x; x.x)	x.x (x.x; x.x)
min max	xx xx	xx xx
Patient is taking anything for hayfever	N=xxx	N=xxx
No	xxx xx.x%	xxx xx.x%
Yes	xxx xx.x%	xxx xx.x%
Oral decongestant	xx	xx
Antihistamine	xx	xx
Oral H antagonist	xx	xx
Intranasal decongestant	xx	xx
Intranasal antihistamine	xx	xx
Intranasal corticosteroid	xx	xx
Intranasal saline	xx	xx
Intraocular antihistamine	xx	xx

Intraocular saline	xx	xx
Patient accepted recommendation	N=xxx	N=xxx
No	xxx xx.x%	xxx xx.x%
Yes	xxx xx.x%	xxx xx.x%
Action Prompt	N=xxx	N=xxx
Patient already using recommended product - Device Technique reviewed	xxx xx.x%	xxx xx.x%
Patient Followed new recommendation and device technique explained/demonstrated	xxx xx.x%	xxx xx.x%
No Recommendation Required	xxx xx.x%	xxx xx.x%

Table 5: Adherence to asthma medications (Intervention group only)

	Baseline (n=xxx)	Month 12 (n=xxx)
A) ALL PARTICIPANTS		
How much of the time do you use ALL of your asthma preventer/controller medications EXACTLY as directed	N=xxx	N=xxx
mean (SD)	xx.x (x.xx)	xx.x (x.xx)
median (Q1; Q3)	x.x (x.x; x.x)	x.x (x.x; x.x)
min max	xx xx	xx xx
How many times in the past 7 days have you used your reliever inhaler	N=xxx	N=xxx
mean (SD)	xx.x (x.xx)	xx.x (x.xx)
median (Q1; Q3)	x.x (x.x; x.x)	x.x (x.x; x.x)
min max	xx xx	xx xx
Number of puffs required to obtain relief	N=xxx	N=xxx
mean (SD)	xx.x (x.xx)	xx.x (x.xx)
median (Q1; Q3)	x.x (x.x; x.x)	x.x (x.x; x.x)
min max	xx xx	xx xx
Appropriate reliever use	N=xxx	N=xxx
No	xxx (xx.x%)	xxx (xx.x%)
Yes	xxx (xx.x%)	xxx (xx.x%)
Adherence VAS score	N=xxx	N=xxx

mean (SD)	xx.x (x.xx)	xx.x (x.xx)
median (Q1; Q3)	x.x (x.x; x.x)	x.x (x.x; x.x)
min max	xx xx	xx xx
Adherence status determined by pharmacist	N=xxx	
Adherent	xxx (xx.x%)	n/a
Non-adherent	xxx (xx.x%)	
B) FOR THOSE WHO ARE NON-ADHERENT		
Concerns about their asthma	N=xxx	N=xxx
No	xxx (xx.x%)	xxx (xx.x%)
Yes	xxx (xx.x%)	xxx (xx.x%)
Information Need	xxx	xxx
Medication Related Concerns	xxx	xxx
Concern about Effect on Co-Morbidities	xxx	xxx
Concern about Effect of Asthma on work or lifestyle	xxx	xxx
Asthma outcome concerns	xxx	xxx
Concerns about Trigger Management	xxx	xxx
Patient knowledge about asthma	N=xxx	N=xxx
Sub-optimal	xxx	xxx
Good	xxx	xxx
Patient understand the difference between reliever and controller/preventer and how their medication work	N=xxx	N=xxx
No	xxx	xxx

Yes	xxx	xxx
How well are your asthma medications working	N=xxx	N=xxx
mean (SD)	xx.x (x.xx)	xx.x (x.xx)
median (Q1; Q3)	x.x (x.x; x.x)	x.x (x.x; x.x)
min max	xx xx	xx xx
Does your asthma medication bother you in any way	N=xxx	N=xxx
No	xxx (xx.x%)	xxx (xx.x%)
Yes	xxx (xx.x%)	xxx (xx.x%)
Adverse effects	xxx	xxx
Beliefs	xxx	xxx
Risk perception	xxx	xxx
Too many medications	xxx	xxx
Any problems remembering to use medications	N=xxx	N=xxx
No	xxx	xxx
Yes	xxx	xxx
Any problems getting repeats filled on time	N=xxx	N=xxx
No	xxx	xxx
Yes	xxx	xxx

Table 6: Inhaler technique (Intervention group only)

	Baseline (n=xxx)	Month 1 (n=xxx)	Month 12 (n=xxx)
Total pMDI technique score	N=xxx	N=xxx	N=xxx
mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
median (Q1; Q3)	x.x (x.x; x.x)	x.x (x.x; x.x)	x.x (x.x; x.x)
min max	xx xx	xx xx	xx xx
Patient mastered technique of pMDI	N=xxx	N=xxx	N=xxx
No	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Yes	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Number of attempts required for pMDI	N=xxx	N=xxx	N=xxx
mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
median (Q1; Q3)	x.x (x.x; x.x)	x.x (x.x; x.x)	x.x (x.x; x.x)
min max	xx xx	xx xx	xx xx
<i>Etc. (repeat for other inhaler types)</i>			

Table 7: Adherence determined via pharmacy dispensing records and PBS linkage

	Control (n=xxx)	Intervention (n=xxx)	Odds ratio ¹ (95% CI)	P-value ¹
A) Baseline				
Pharmacy records	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)		
PBS	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)		
B) Month 12				
Pharmacy records	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)	xx.xx (xx.xx to xx.xx)	0.xxx
PBS	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)	xx.xx (xx.xx to xx.xx)	0.xxx

Notes:

Adherence defined as follows: MPR >80% for each preventer medication.

1. OR and p-value obtained from logistic regression model with a fixed intervention effect and a random pharmacy effect

Table 8: Changes in medications

	Control N (%)	Intervention N (%)	Odds ratio (95% CI)	P-value
Month 1				
Referral made at prior session	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)	xx.xx (xx.xx to xx.xx)	0.xxx
Seen doctor for asthma since last visit	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)	xx.xx (xx.xx to xx.xx)	0.xxx
Updates regarding asthma therapy	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)	xx.xx (xx.xx to xx.xx)	0.xxx
Medication ceased	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)	xx.xx (xx.xx to xx.xx)	0.xxx
New medication added	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)	xx.xx (xx.xx to xx.xx)	0.xxx
Dose increase	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)	xx.xx (xx.xx to xx.xx)	0.xxx
Dose decrease	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)	xx.xx (xx.xx to xx.xx)	0.xxx
Other	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)	xx.xx (xx.xx to xx.xx)	0.xxx
Month 12 ¹				
Referral made at prior session	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)	xx.xx (xx.xx to xx.xx)	0.xxx
Seen doctor for asthma since last visit	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)	xx.xx (xx.xx to xx.xx)	0.xxx
Updates regarding asthma therapy	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)	xx.xx (xx.xx to xx.xx)	0.xxx
Medication ceased	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)	xx.xx (xx.xx to xx.xx)	0.xxx
New medication added	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)	xx.xx (xx.xx to xx.xx)	0.xxx
Dose increase	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)	xx.xx (xx.xx to xx.xx)	0.xxx
Dose decrease	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)	xx.xx (xx.xx to xx.xx)	0.xxx
Other	xxx/XXX (xx.x%)	xxx/XXX (xx.x%)	xx.xx (xx.xx to xx.xx)	0.xxx

1. Changes reported at month 12 include any change made after Month 1. For Intervention subjects, this includes any change recorded at the Month 6 visit.

Figure 2: ACQ score

Figure 3: RACT score

Figure 4: AQOL score

Figure 5: SF12 MH score

Figure 6: SF12 PH score

Programming note: For figures 2-6, create a box plot by visit (baseline, Month 1 and Month 12), with one box for each group at each visit. Add boxes at Month 6 for the ACQ.

Figure 7: % with Asthma control

Figure 8: % with asthma plan at Month 12

Figure 9: % using reliever at Month 12

Programming note: For Figures 7-9, create bar chart by visit with one bar per group. For Asthma plan and reliever use, possible to combine two figures into one figure with two panels given only a single visit.

Table 9: ACQ questions by visit

	Control (n=xxx)	Intervention (n=xxx)	All (n=xxx)
BASELINE			
How often were you woken by your asthma during the night?	N=xxx	N=xxx	N=xxx
<i>Not at all</i>	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
<i>Hardly ever</i>	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
<i>A few times</i>	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
<i>Several times</i>	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
<i>Many times</i>	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
<i>A great many times</i>	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
<i>Unable to sleep because of asthma</i>	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
How were your asthma symptoms when you woke up in the morning?	N=xxx	N=xxx	N=xxx
<i>No symptoms</i>	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
<i>Very mild symptoms</i>	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
<i>Mild symptoms</i>	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
<i>Moderate symptoms</i>	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
<i>Quite severe symptoms</i>	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
<i>Severe symptoms</i>	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
<i>Very severe symptoms</i>	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Etc. (repeat for remaining questions)
MONTH 1
...
MONTH 6
...
MONTH 12
...

Table 10: AQOL questions by visit

Table 11: RCAT questions by visit

Table 12: SF12 questions by visit

Programming note: same format as for ACQ excluding the Month 6 visit.

Table 13: Analysis of primary and secondary outcomes

	Control % or mean (SE) ¹	Intervention % or mean (SE) ¹	OR or MD (95% CI) ¹	P value	Analysis type ²
% with ACQ <1.5					
Month 1	xxx (xx.x)	xxx (xx.x)	xx.xx (xx.xx; xx.xx)	0.xxx	U ^B
Month 6	xxx (xx.x)	xxx (xx.x)	xx.xx (xx.xx; xx.xx)	0.xxx	U ^B
Month 12 ³	xxx (xx.x)	xxx (xx.x)	xx.xx (xx.xx; xx.xx)	0.xxx	U ^B
	xxx (xx.x)	xxx (xx.x)	xx.xx (xx.xx; xx.xx)	0.xxx	A
	xxx (xx.x)	xxx (xx.x)	xx.xx (xx.xx; xx.xx)	0.xxx	MI
ACQ score					
Month 1	xxx (xx.x)	xxx (xx.x)	xx.xx (xx.xx; xx.xx)	0.xxx	U ^B
Month 1 - baseline	xxx (xx.x)	xxx (xx.x)			
Month 12	xxx (xx.x)	xxx (xx.x)	xx.xx (xx.xx; xx.xx)	0.xxx	U ^B
Month 12 - baseline	xxx (xx.x)	xxx (xx.x)			
AQOL score					
Month 1	xxx (xx.x)	xxx (xx.x)	xx.xx (xx.xx; xx.xx)	0.xxx	U ^B
Month 1 - baseline	xxx (xx.x)	xxx (xx.x)			
Month 12	xxx (xx.x)	xxx (xx.x)	xx.xx (xx.xx; xx.xx)	0.xxx	U ^B
Month 12 - baseline	xxx (xx.x)	xxx (xx.x)			
RCAT score					
Month 1	xxx (xx.x)	xxx (xx.x)	xx.xx (xx.xx; xx.xx)	0.xxx	U ^B
Month 1 - baseline	xxx (xx.x)	xxx (xx.x)			

Month 12	xxx (xx.x)	xxx (xx.x)	xx.xx (xx.xx; xx.xx)	0.xxx	U ^B
Month 12 - baseline	xxx (xx.x)	xxx (xx.x)			
% with asthma action plan					
Month 12	xxx (xx.x)	xxx (xx.x)	xx.xx (xx.xx; xx.xx)	0.xxx	U
% using preventer therapy					
Month 12	xxx (xx.x)	xxx (xx.x)	xx.xx (xx.xx; xx.xx)	0.xxx	U

All analyses performed using repeated measure mixed models – either linear or logistic – with a fixed effect of the intervention, a fixed effect of the visit (Month 1 or 12), a fixed intervention by visit interaction and a random intercept by pharmacy. Depending on the outcome, the base/unadjusted model also includes the baseline value of the outcome (e.g. baseline ACQ score), this is indicated by the analysis type U^B.

- Means or percentages are predicted from the linear or logistic model using the average baseline values. SE = standard error; OR = odds ratio; MD = mean difference; CI = confidence interval
- Analysis type:
U = unadjusted model without the baseline value of the outcome
U^B = unadjusted model with the baseline value of the outcome (continuous)
A = Adjusted model including the following covariates: *<to be completed once known>*
MI = Multiple imputation analysis
- The boxed row corresponds to the primary analysis of the primary endpoint

Programming notes:

- The variables included in the adjusted model will be determined using univariate analyses and by comparing baseline characteristics.*
- Multiple imputation is optional depending on the % with missing values.*

Table 14: Hospital admissions, ED presentations and GP visits in the past 12 months

	Control (n=xxx)	Intervention (n=xxx)	Adjusted mean difference (95% CI)	p-value ¹
BASELINE				
Number of accidents or Emergency visits for asthma	N=xxx	N=xxx		
mean (SD)	xxx (xxx)	xxx (xxx)		
median (Q1-Q3)	xxx (xx-xx)	xxx (xx-xx)		
min – max	xxx - xxx	xxx - xxx		
Number of hospital admissions for asthma	N=xxx	N=xxx		
mean (SD)	xxx (xxx)	xxx (xxx)		
median (Q1-Q3)	xxx (xx-xx)	xxx (xx-xx)		
min – max	xxx - xxx	xxx - xxx		
Number of GP visits	N=xxx	N=xxx		
mean (SD)	xxx (xxx)	xxx (xxx)		
median (Q1-Q3)	xxx (xx-xx)	xxx (xx-xx)		
min – max	xxx - xxx	xxx - xxx		
MONTH 12				
Number of accidents or Emergency visits for asthma	N=xxx	N=xxx		
mean (SD)	xxx (xxx)	xxx (xxx)	xx.x (xx.x to xx.x)	0.xxx
median (Q1-Q3)	xxx (xx-xx)	xxx (xx-xx)		
min – max	xxx - xxx	xxx - xxx		
Number of hospital admissions for asthma	N=xxx	N=xxx		

mean (SD)	xxx (xxx)	xxx (xxx)	xx.x (xx.x to xx.x)	0.xxx
median (Q1-Q3)	xxx (xx-xx)	xxx (xx-xx)		
min – max	xxx - xxx	xxx - xxx		
Number of GP visits	N=xxx	N=xxx		
mean (SD)	xxx (xxx)	xxx (xxx)	xx.x (xx.x to xx.x)	0.xxx
median (Q1-Q3)	xxx (xx-xx)	xxx (xx-xx)		
min – max	xxx - xxx	xxx - xxx		

Number of accidents or emergency visits and number of hospital admissions obtained as part of the direct data collection; GP visits obtained via MBS linkage

1. P-value from a random-effect analysis of covariance with the outcome at 12 months as the dependent variable and the following variables as independent variables: a fixed effect of the intervention, a fixed effect of the baseline value of the outcome and a random effect of the pharmacy to adjust for clustering.

Figure 10: Distribution of ACQ scores at Month 12, by treatment group

Histogram with one panel per arm (and one bar per possible value)

Figure 11: Forest plot for subgroup analysis of asthma control at 12 month