The Children's Anti-inflammatory REliever (CARE) study: a protocol for a randomised controlled trial of budesonide-formoterol as sole reliever therapy in children with mild asthma

Supplementary material

Asthma action plans and logbooks

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### Figure S1: Budesonide-formoterol (Symbicort Rapihaler®): Step 1

| ASTHMA ACTION PLAN | SYMBOICORT |
|--------------------|------------|
| **Know your asthma symptoms** | **Know when and how to take your puffers** |
| **Feeling well** | **Remember…** |
| Your asthma is under control when… | - Take 2 puffs of your Symbicort through a spacer when you wheeze, cough, or find it hard to breathe |
| - You do not have asthma symptoms most days (wheeze, tight chest, cough, or find it hard to breathe) | - Take 2 puffs of your Symbicort through a spacer if you find it hard to breathe when you exercise or play |
| - You can play just like other children | |
| - Most days you do not need your Symbicort | |

| **Getting worse** | **Let’s take action…** |
| Your asthma is getting worse when… | - You need to see your doctor within the next week to change the way you use your puffer |
| - You coughing or wheezing more | - Take 2 puffs of your Symbicort through a spacer as often as needed to relieve symptoms |
| - OR you wake up at night because of your asthma | |
| - OR You are using more than 6 puffs a day, for one week | |

| **Feeling worried** | **Let’s get help…** |
| Your asthma is a worry when… | - You need to go to the hospital or see your doctor today |
| - You are breathing fast or find it hard to breathe | - Take 2 puffs of your Symbicort through a spacer as often as needed to relieve symptoms |
| - OR your Symbicort is only helping for 2-3 hours | |
| - OR you are using more than 12 puffs of Symbicort a day | |
| - OR you feel you need to see your doctor | |

| **Emergency** | **Let’s keep calm…** |
| Your asthma is an emergency when… | - Dial 111 for an ambulance and tell them you’re having a severe asthma attack |
| - Your symptoms are getting more severe quickly | - Sit upright and try to stay calm |
| - OR you are finding it hard to speak or breathe | - Take 2 puffs of Symbicort through a spacer, taking 6 breaths for each puff, as often as needed until help arrives |
| - OR you look pale or blue | - Even if you seem to get better, seek medical help right away |
| - OR your Symbicort is not helping | |
| - OR you are using your Symbicort every 1-2 hours | |
| - OR you are using more than 16 puffs a day | |

**Study details**

| Next appointment dates |
|------------------------|
| Visit 2 | |
| Visit 3 | |
| Visit 4 | |
| Visit 5 | |

**Study contact**

| Name | Phone | Email |
|------|-------|-------|

**Medical help**

If you need medical help for your asthma, please contact your GP. After Hours service, or 111 as appropriate. This is important to make sure you get treated quickly.
# How to use your inhaler with a spacer

When using a metered dose inhaler (MDI), a spacer will help get the right dose of medicine into your lungs. Remember not to share your spacer with anyone else.

1. Hold the inhaler upright and give it a good shake.
2. Fit the inhaler into the opening at the end of the spacer.
3. Seal lips firmly around the mouthpiece, and press the inhaler once only.
4. Take 6 slow breaths in and out through your mouth. Do not remove the spacer from your mouth between breaths.
5. Remove the spacer from your mouth.
6. Repeat steps 1-4 for further doses.
7. Rinse your mouth with water or brush your teeth after using your Symbicort puffer.

## Washing your spacer

Wash your spacer once a week with warm water and dishwashing liquid. **Leave to drip dry (do not rinse).** This will ensure that your medicine gets into your lungs and does not stick to the sides of the spacer.

## Since your last visit...

### Have you taken any days off school or work due to asthma?

| Start date | End date | How many days? | Did someone take time off work due to your asthma? | How many people took time off work due to your asthma? | Who were they? | How many days did each person take off work? |
|------------|----------|----------------|----------------------------------------------------|--------------------------------------------------------|---------------|---------------------------------------------|
| ...        | ...      | ...            | ...                                                | ...                                                    | ...           | ...                                         |

### Have you started any new medication (other than prednisone) OR changed any existing medication?

| Medication started/changed | Dose | How many times a day? | How long for? | Date started/changed | Date stopped | Reason for medication |
|---------------------------|------|-----------------------|---------------|----------------------|--------------|-----------------------|
| ...                       | ...  | ...                   | ...           | ...                  | ...          | ...                   |

### Have you visited your doctor (e.g. GP) or been admitted to hospital due to asthma?

| Date       | Type of visit | Was prednisone given? | Dose of Prednisone | How long for? | Start date | Stop date | Comments |
|------------|---------------|-----------------------|-------------------|---------------|------------|-----------|----------|
| ...        | ...           | ...                   | ...               | ...           | ...        | ...       | ...      |
**Figure S2: Budesonide-formoterol (Symbicort Rapihaler®): Steps 2 and 3**

### ASTHMA ACTION PLAN | SYMBOCORT

#### Know your asthma symptoms

| Feeling well | Your asthma is under control when... |
|--------------|-------------------------------------|
|              | • You do not have asthma symptoms most days (wheeze, tight chest, cough, or find it hard to breathe) |
|              | • You can play just like other children |
|              | • Most days you do not need your Symbicort |

| Getting worse | Your asthma is getting worse when... |
|---------------|-------------------------------------|
|               | • You coughing or wheezing more |
|               | • OR you wake up at night because of your asthma |
|               | • OR You are using more than 6 puffs a day, for one week |

| Feeling worried | Your asthma is a worry when... |
|----------------|-------------------------------|
|                | • You are breathing fast or find it hard to breathe |
|                | • OR your Symbicort is only helping for 2-3 hours |
|                | • OR you are using more than 12 puffs of Symbicort a day |
|                | • OR you feel you need to see your doctor |

| Emergency | Your asthma is an emergency when... |
|-----------|-----------------------------------|
|           | • Your symptoms are getting more severe quickly |
|           | • OR you are finding it hard to speak or breathe |
|           | • OR you look pale or blue |
|           | • OR your Symbicort is not helping |
|           | • OR you are using your Symbicort every 1-2 hours |
|           | • OR you are using more than 16 puffs a day |

#### Know when and how to take your puffers

| Remember... |
|-------------|
| Preventer and reliever: |
| Symbicort |
| 2 puffs when needed to relieve symptoms |

#### Know your puffers

- The name of your puffer is **Symbicort**.
  **The colour is red**
- Your Symbicort is both a preventer and a reliever puffer
- You take this everyday even when you are well, and when you need it
- You should **carry your Symbicort** with you at all times
- You should always use a spacer with your Symbicort

### Study details

| Next appointment dates |
|------------------------|
| Visit 2 |
| Visit 3 |
| Visit 4 |
| Visit 5 |

| Study contact |
|---------------|
| Name          |
| Phone         |
| Email         |

| Medical help |
|--------------|
| If you need medical help for your asthma, please contact your GP, After Hours service, or 111 as appropriate. This is important to make sure you get treated quickly. |
### How to use your inhaler with a spacer

When using a metered dose inhaler (MDI), a spacer will help get the right dose of medicine into your lungs. Remember not to share your spacer with anyone else.

1. Hold the inhaler upright and give it a good shake.
2. Fit the inhaler into the opening at the end of the spacer.
3. Seal lips firmly around the mouth piece, and press the inhaler once only.
4. Take 6 slow breaths in and out through your mouth. Do not remove the spacer from your mouth between breaths.
5. Remove the spacer from your mouth.
6. Repeat steps 1-4 for further doses.
7. Rinse your mouth with water or brush your teeth after using your Symbicort puffer.

### Washing your spacer

Wash your spacer once a week with warm water and dishwashing liquid.

### Leave to drip dry (do not rinse).

This will ensure that your medicine gets into your lungs and does not stick to the sides of the spacer.

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### Since your last visit...

**Have you taken any days off school or work due to asthma?**

| Start date | End date | How many days? | Did someone take time off work due to your asthma? | How many people took time off work due to your asthma? | Who were they? | How many days did each person take off work? |
|------------|----------|----------------|---------------------------------------------------|-------------------------------------------------------|--------------|---------------------------------------------|
| e.g. 16/09/2020 | e.g. 18/09/2020 | e.g. 3 | e.g. Yes | e.g. 2 - me and mum | e.g. Me 2 days, Mum 1 day |

**Have you started any new medication (other than prednisone) OR changed any existing medication?**

| Medication started/changed | Dose | How many times a day? | How long for? | Date started/changed | Date stopped | Reason for medication |
|----------------------------|------|-----------------------|--------------|----------------------|--------------|-----------------------|
| e.g. Amoxicillin           | e.g. 500mg | e.g. 3 | e.g. 5 days | e.g. 15/09/2020 | e.g. 20/09/2020 | e.g. Sore throat |

**Have you visited your doctor (e.g. GP) or been admitted to hospital due to asthma?**

| Date | Type of visit | Was prednisone given? | Dose of Prednisone | How long for? | Start date | Stop date | Comments |
|------|---------------|-----------------------|-------------------|--------------|------------|-----------|----------|
| e.g. 15/09/2020 | e.g. ED visit | e.g. Yes | e.g. 40mg | e.g. 4 days | e.g. 15/09/2020 | e.g. 19/09/2020 | e.g. Admitted |
Figure S3: Salbutamol (Ventolin®): Step 1

**Care Action Plan: Ventolin**

**Know your asthma symptoms**

**Feeling well**
- Your asthma is under control when...
  - You do not have asthma symptoms most days (wheeze, tight chest, cough, or find it hard to breathe)
  - You can play just like other children
  - Most days you do not need your Ventolin

**Feeling worse**
- Your asthma is getting worse when...
  - You coughing or wheezing more
  - OR you wake up at night because of your asthma
  - OR You are using more than 6 puffs a day, for one week

**Feeling worried**
- Your asthma is a worry when...
  - You are breathing fast or find it hard to breathe
  - OR your Ventolin is only helping for 2-3 hours
  - OR you are using more than 12 puffs of Ventolin a day
  - OR you feel you need to see your doctor

**Emergency**
- Your asthma is an emergency when...
  - Your symptoms are getting more severe quickly
  - OR you are finding it hard to speak or breathe
  - OR you look pale or blue
  - OR your Ventolin is not helping
  - OR you are using your Ventolin every 1-2 hours
  - OR you are using more than 16 puffs a day

**Know when and how to take your puffers**

**Remember...**
- Take 2 puffs of your Ventolin through a spacer when you wheeze, cough, or find it hard to breathe
- Take 2 puffs of your Ventolin through a spacer if you find it hard to breathe when you exercise or play

**Let's take action...**
- You need to see your doctor within the next week to add a preventer puffer
- Take 2 puffs of your Ventolin through a spacer as often as needed to relieve symptoms

**Let's get help...**
- You need to go to the hospital or see your doctor today
- Take 2 puffs of your Ventolin through a spacer as often as needed to relieve symptoms

**Let's keep calm...**
- Dial 111 for an ambulance and tell them you're having a severe asthma attack
- Sit upright and try to stay calm
- Take 6 puffs of Ventolin through a spacer every 6 minutes with 6 breaths for each puff until help arrives
- Even if you seem to get better, seek medical help right away

**Know your puffers**
- The name of your reliever puffer is Ventolin. The colour is blue
- You take this puffer only when you need it
- You should carry your Ventolin with you at all times
- You should always use a spacer with your Ventolin and take 6 breaths for each puff

**Study details**

**Next appointment dates**
- Visit 2
- Visit 3
- Visit 4
- Visit 5

**Study contact**
- Name __________________________
- Phone __________________________
- Email __________________________

**Medical help**
- If you need medical help for your asthma, please contact your GP. After Hours service, or 111 as appropriate. This is important to make sure you get treated quickly.
How to use your inhaler with a spacer

When using a metered dose inhaler (MDI), a spacer will help get the right dose of medicine into your lungs. Remember not to share your spacer with anyone else.

1. Hold the inhaler upright and give it a good shake.
2. Fit the inhaler into the opening at the end of the spacer.
3. Seal lips firmly around the mouthpiece, and press the inhaler once only.
4. Take 6 slow breaths in and out through your mouth. Do not remove the spacer from your mouth between breaths.
5. Remove the spacer from your mouth.
6. Repeat steps 1-4 for further doses.

Washing your spacer

Wash your spacer once a week with warm water and dishwashing liquid.

Leave to drip dry (do not rinse). This will ensure that your medicine gets into your lungs and does not stick to the sides of the spacer.

Since your last visit...

Have you taken any days off school or work due to asthma?

| Start date | End date | How many days? | Did someone take time off work due to your asthma? | How many people took time off work due to your asthma? | Who were they? | How many days did each person take off work? |
|------------|----------|----------------|-----------------------------------------------|---------------------------------------------------|---------------|---------------------------------------------|
| e.g. 16/09/2020 | e.g. 18/09/2020 | e.g. 3 | e.g. Yes | e.g. 2 - me and mum | e.g. Me 2 days, Mum 1 day |

Have you started any new medication (other than prednisone) OR changed any existing medication?

| Medication started/changed | Dose | How many times a day? | How long for? | Date started/changed | Date stopped | Reason for medication |
|----------------------------|------|-----------------------|--------------|---------------------|--------------|-----------------------|
| e.g. Amoxicillin | e.g. 500mg | e.g. 3 | e.g. 5 days | e.g. 15/09/2020 | e.g. 20/09/2020 | e.g. Sore throat |

Have you visited your doctor (e.g. GP) or been admitted to hospital due to asthma?

| Date | Type of visit | Was prednisone given? | Dose of Prednisone | How long for? | Start date | Stop date | Comments |
|------|--------------|-----------------------|-------------------|--------------|------------|----------|----------|
| e.g. 15/09/2020 | e.g. ED visit | e.g. Yes | e.g. 40mg | e.g. 4 days | e.g. 15/09/2020 | e.g. Admitted |
Figure S4: Salbutamol (Ventolin®): Steps 2 and 3

**Asthma Action Plan | Ventolin**

**Know your asthma symptoms**
- Your asthma is under control when...
  - You do not have asthma symptoms most days (wheezy, tight chest, cough, or find it hard to breathe)
  - You can play just like other children
  - Most days you do not need your Ventolin

- Your asthma is getting worse when...
  - You coughing or wheezing more
  - OR you wake up at night because of your asthma
  - OR you are using more than 6 puffs a day, for one week

- Your asthma is a worry when...
  - You are breathing fast or find it hard to breathe
  - OR your Ventolin is only helping for 2-3 hours
  - OR you are using more than 12 puffs of Ventolin a day
  - OR you feel you need to see your doctor

- Your asthma is an emergency when...
  - Your symptoms are getting more severe quickly
  - OR you are finding it hard to speak or breathe
  - OR you look pale or blue
  - OR your Ventolin is not helping
  - OR you are using your Ventolin every 1-2 hours
  - OR you are using more than 16 puffs a day

**Know when and how to take your puffers**
- Your inhalers are...
  - Preventer: ___ puffs(s) every morning
  - ___ puffs(s) every night
  - Reliever: Ventolin 2 puffs when needed to relieve symptoms

**Know your puffers**
- Preventer: You take this everyday even when you’re well. The name of your preventer is ___________. The colour is ___________.
- Reliever: You take this only when you need it. The name of your reliever is Ventolin. The colour is blue.

- You should carry your Ventolin with you at all times
- You should always use a spacer with your puffers

**Study details**

| Next appointment dates |
|------------------------|
| Visit 2                |
| Visit 3                |
| Visit 4                |
| Visit 5                |

**Study contact**

Name __________________________
Phone __________________________
Email __________________________

**Medical help**
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**How to use your inhaler with a spacer**

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3. Seal lips firmly around the mouthpiece, and press the inhaler once only.
4. Take 6 slow breaths in and out through your mouth. Do not remove the spacer from your mouth between breaths.
5. Remove the spacer from your mouth.
6. Repeat steps 1–4 for further doses.
7. Rinse your mouth with water or brush your teeth after using your preventer puffer.

**Washing your spacer**

Wash your spacer once a week with warm water and dishwashing liquid.

**Leave to drip dry (do not rinse).** This will ensure that your medicine gets into your lungs and does not stick to the sides of the spacer.

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**Since your last visit...**

- **Have you taken any days off school or work due to asthma?**

| Start date | End date | How many days? | Did someone take time off work due to your asthma? | How many people took time off work due to your asthma? | Who were they? | How many days did each person take off work? |
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| e.g. 16/09/2020 | e.g. 18/09/2020 | e.g. 3 | e.g. Yes | e.g. 2 - me and mum | e.g. Me 2 days, Mum 1 day |

- **Have you started any new medication (other than prednisone) OR changed any existing medication?**

| Medication started/changed | Dose | How many times a day? | How long for? | Date started/changed | Date stopped | Reason for medication |
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| e.g. Amoxicillin | e.g. 500mg | e.g. 3 | e.g. 5 days | e.g. 15/09/2020 | e.g. 20/09/2020 | e.g. Sore throat |

- **Have you visited your doctor (e.g. GP) or been admitted to hospital due to asthma?**

| Date | Type of visit | Was prednisone given? | Dose of Prednisone | How long for? | Start date | Stop date | Comments |
|------|---------------|-----------------------|-------------------|--------------|------------|----------|----------|
| e.g. 15/09/2020 | e.g. ED visit | e.g. Yes | e.g. 40mg | e.g. 4 days | e.g. 15/09/2020 | e.g. 19/09/2020 | e.g. Admitted |