Appendix 1

Inhaler Proficiency Schedule (IPS)

Patient ID: _____

Date: _____

Visit No: _____

	YES	NO
Does the patient hold the outer casing of the inhaler in one hand, whilst pushing the thumb grip away, until a click is heard?		
Does the patient hold the inhaler with mouthpiece towards himself?		
Does the patient slide lever away until it clicks?		
Does the patient hold the inhaler in a horizontal position?		
Does the patient breath out slowly and then put inhaler in front of mouth?		
Does the patient place mouthpiece between lips and breathe in as deeply as possible?		
Does the patient remove inhaler from mouth and hold breath for about 10 seconds?		
After 10 seconds does the patient breathe out slowly?		
Does the patient close the inhaler by sliding thumb grip back towards himself as far as it will go until it clicks?		
Does the patient gargle throat after use?		

Appendix 2

Clinical Training Manual

Including examples

Please note – throughout the manual, established behaviour change techniques are noted in parentheses, in accordance with the Behaviour Change Taxonomy (Michie et al., The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions. Ann Behav Med 2013, 46: 81-95)

Summary

The "Best practice care" group

The principal themes of "Best practice care" group are:

1. Asthma education (nature of disease and need for treatment) and discussion on adherence, including-strategies to enhance adherence e.g. reminders and goal setting.

2. Training on inhaler use till proficient, as demonstrated with an Inhaler Proficiency Score (IPS, see appendix 2) observational score.

3. Advice on allergen or trigger avoidance; as related to PEFR.

The INCA group

The core features are listed:

1. The patient's treatment goal is established and used as the focus of the conversation. [This goal is to be referred to at each visit]

2. Data from the INCA device including (1) time of use, (2) pattern of using, to maximise habit forming (3) handling proficiency including inhalation flow rates are discussed, with graphs as shown in figure 2. These are aimed to enhance the value of the inhaler.

3. Data from the hand held PEFR, reliever use and AQLQ are correlated with the adherence so that these can be used to account for improvements or declines in these measures, to identify triggers

Screening visit/ Randomisation visit

Active and Control

"Tell me about your asthma and its treatment"

Opens the goals for treatment discussion, the rationale for treatment, and the inhaler technique.

All will have asthma explained as follows:

"Asthma is a clinical disease where the airways are irritated and swollen by dust, viruses, pollens and pollution. This irritation causes narrowing of the air passages which leads to you feeling tight, wheezy and short of breath" [5.1, 9.1]

All will have asthma treatment explained:

"Asthma is treated with an inhaler which has medicines which open the airways, to reduce the feelings of tightness and shortness of breath as well as a medicine which relieves the irritation, a steroid. The treatment that seems to work best is an inhaler that has two medicines, one to open the airways and the other lessens the inflammation and together they are very effective at treating most people's asthma. We think that using this type of medicine regularly helps keep you well"

"Any questions?"

"Are you happy with this explanation?"

Then:

"What would you say your goals for getting better are? List up to three, as specific as possible" [1.3].

Then:

At Visit 1 all participants (Active and Control) will demonstrate their INHALER TECHNIQUE and will be educated accordingly using the teach-to-goal approach. The IPS score after training will be recorded, **aiming** to reach 9/10. [6.1; 4.1].

Then:

All are shown how to use the PEFR meter [6.1.; 4.1].

At this visit, the physiological, clinical, past history and health status questionnaires are collected, see CRF.

Visits 2 to 4; every 4 weeks (21-30 days) for 12 weeks.

Control Group

Reviews progress over the last month

"How did you get on and how are you?"

"Have you been to the Doctor for your chest in the last month?"

Review of ACT, AQLQ peak flow measurements [2.2.;2.7.]

"How have you been getting on with your inhaler?"

This is an opportunity to promote strategies to encourage inhaler adherence e.g. try and identify some regular routine that the participant frequently does and tie in taking their inhaler at that time. For example "What time do you have dinner?" "Go to bed?" "Watch the news?" Link these to inhaler use. [7.1.;8.1.;8.3.]

INCA ACTIVE Group

"How did you get on and how are you?"

"Have you been to the Doctor for your chest in the last month?

Review of primary goals [1.7, possibly 1.6]. The old and the current ACT score is the focus of the discussion.

"What was it about your **asthma**/**health**/**goals** that you want to make better?"

"To achieve these aims need you to use your inhaler as best you can. It's really only after a few months of this that we can really see a big impact, eg changing/reducing your medication use."

"To get these goals, let us see if we can help you get the most from your inhaler."

Step 1 Doses/ timings graph (Figure 2). Focus on the positive aspects [2.7, 10.4]. For example "Well done you remember to take your inhaler most days ", or, "you are steady in the morning times, showing you have a good routine but the evening needs a little work". Try to identify some regular routine that the participant frequently does and tie in taking their inhaler at that time. For example "What time do you have dinner?" "Go to bed?" "Watch the news?" [7.1,8.1,8.3]. This is an opportunity to discuss barriers [1.2, possibly 12.1,

12.2] to regular inhaler use with the patient and for them to make suggestions on how they can link inhaler use with their asthma progress [5.1.;2.2].

Step 2. From the graphs, the errors are identified including exhalation, low peak inspiratory flow rates (peak inspiratory flow rate achieved on using the inhaler. If there was an error in handling the salmeterol/fluticasone inhaler this can be corrected using the teach-to-goal technique [4.1.]. If there are examples of low inspiratory flow then these are pointed out and further training, eg with the Clement Clark device is given. [2.2, 2.6]

Step 3 is the PEFR readings.–The day to day peak to trough variation and The weekly trend as well as (going up, staying the same, getting better) can then be related to the inhaler use, (going up, staying the same, getting better). [2.6.]

These data provide a point for the patient to discuss the outcomes in relation to their own life, e.g. if they were away, were in stressful situations, if they developed a URI, etc. [1.5]

Step 4. Inhaler reliever inhaler use. This is collected on the second INCA device, which is attached to a salbutamol inhaler. Note, the use of a reliever has been shown to be a good surrogate of adherence.

Step 5 combination graph where all the information on adherence, PEFR and symptoms are collated. These graphs provide a point for the patient to discuss reliever use in relation to their own life, eg if they were breathless, were in stressful situations [4.2], if they developed a URI, and if these coincide with PEFR changes or prior poor adherence [1.5] or if falling rates of inhaler use reflect increasing adherence to preventer therapy. This can be used as a reminder and a tool for discussing possible causes of exacerbations or loss of asthma control [1.5, 1.7].