Qualitative Report

A Qualitative Evaluation Study to Explore the Use of Temperature Controlled Laminar Airflow (TLA) in the Treatment of Severe Allergic Asthma and Participant's Experience of Taking Part in the LASER Trial during the 4 month Pilot Phase

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Background

The LASER Trial is a randomised, double blind, placebo-controlled, parallel group trial of the effectiveness of the nocturnal use of a Temperature-controlled Laminar Airflow (TLA) Device (Airsonett®) in adults with poorly-controlled, severe allergic asthma.

The trial is funded by the NIHR- Health Technology Assessment Programme (12/33/28) and is being conducted at 7 centres across the UK. The trial aims to determine whether home-based nocturnal treatment with a TLA device can reduce the frequency of severe asthma exacerbations over a one year period. In addition to this, secondary quantitative outcome measures include changes in asthma control, lung function, asthma-specific and global quality of life for participants and their carers, adherence to the intervention, healthcare resource use and costs, and cost-effectiveness.

In order to inform decisions about implementation of the device should it be shown to be effective, participant's experience of using the TLA device is being assessed by means of qualitative interviews. Qualitative interviews are also being conducted with trial participants' partners (defined as adults living in the same home and sharing the same bedroom environment as the trial participant) as it is important to determine whether the treatment is acceptable to all parties whose life will be affected by the treatment device.

In the initial 4 month pilot phase of the trial, qualitative interviews have been conducted by telephone to meet the following objectives:

1. Assess trial processes
2. Assess participant's experience of using the TLA device.
3. Identify potential barriers to treatment adherence
4. Identify potential barriers to recruitment and retention of participants.

Results of the interviews will be used to:

1. Inform subsequent development and refinement of trial processes (Study Visits, Trial Paperwork and Trial Website www.lasertrial.co.uk)
2. Strengthen the Frequently Asked Questions area of the LASER Trial website.
3. Inform the topic guide for the later focus group interviews.

Focus group interviews will be held at the end of the participants 12 month trial period to gather further information about device acceptability and experience of device use over a longer period.

Summary

This report describes the findings from a qualitative evaluation study to ascertain trial participant's views of the LASER trial processes and their experience of using the Temperature-controlled Laminar Airflow (TLA) Device (Airsonett®) during the 4 month pilot phase of The LASER Trial. This information will allow us to assess trial processes and make practical modifications to enhance participant experience during the remainder of the trial.

Telephone interviews took place during the initial 4 month pilot phase of the trial, between September and October 2014. A total number of 12 interviews were conducted (10 participants / 2 Partners.)

This report is based on a small purposive sample of 12 participants. With any qualitative research it is unlikely that the comments received can be generalised to include all participants in the trial and users of the treatment device. Nevertheless, the responses received represent a range of participants and describe their experience of the delivery of the trial and of the TLA treatment device. The main findings are provided below.

Summary of Interview Findings:

Motivation for Participation

Participants gave a variety of different reasons for taking part in the LASER Trial. The most common reason was to help improve asthma control and reduce the risk of exacerbations and hospital admissions. This was seen as beneficial to the trial participant themselves as well as to future users of the device and patients with asthma.

Participants also saw the trial as an opportunity to learn more about their asthma.

This trial was seen as being different to other clinical trials by virtue of the fact that it is testing a non-pharmaceutical treatment and that it is an additional treatment to be used alongside current asthma treatments.

Information Events

The information events were well received. Participants enjoyed the opportunity to meet other patients with asthma and the opportunity to discuss the trial with members of the trial team.

Participants who attended the event with other family members felt that this was useful so that everyone was fully informed of what participation in the trial would involve.

The information events were also seen as a useful educational opportunity.

Information Packs / Participant Information Sheet (PIS)

All participants found the information sheet easy to read and accessible. They all felt that they had been given adequate time to read the information and come to an informed decision before signing the consent form.

Participants were given ample opportunity to ask questions.

A device template was included in the Information Pack to reassure participants that the device would fit into their bedroom. Participants found the device template to be particularly useful however one participant noted that there was no explanation of which orientation the template should be used in.

Trial Visits 1 & 2

Some participants found that the initial study visits took longer than expected. Participants should be informed that the initial visit can take up to 90 minutes so that adequate time can be scheduled for the visit.

Participants are familiar with the tests being performed in the trial due to their usual clinical

visits and so they were happy with performing the various tests required for assessment of eligibility.

Participants were happy with paperwork completion and questionnaires although one participant found that the volume of paperwork was burdensome.

Device Delivery / Installation

Device delivery and installation generally went smoothly and delivery was scheduled at a convenient time for the majority of participants.

Two participants however had problems with their delivery teams not being competent to deliver and install the device. These issues have been addressed with the company and measures have been taken to help prevent similar experiences for future trial participants.

All participants were able to accommodate the treatment device in their bedroom but 6 had to make minor modifications. 3 had to move bedside tables and 3 had to move their bed to accommodate the device. Participants will be informed of the possible need for bedroom modification in order to accommodate the device before device delivery to ensure that they are happy with this.

Website

Nine of the ten participants had used the website at least once but of these most had only used the website once or at the start of the trial and had not returned to re-visit the site.

Participants felt that a forum where they could share experiences would be a useful use of the website.

The TLA Device

Participants made several suggestions about how the device could be modified for future users.

Most participants commented on the size of the device and would like it to be reduced in size and if possible made portable.

One participant suggested that it would be useful if it was possible to rotate the neck of the device. This would make changing the bed easier and allow the device's 'airshower' to be moved out of the way when necessary without having to move the base of the device.

Three participants found the shelf to be a useful design feature but that the shelf was too small to accommodate what would otherwise be stored on a bedside table.

Participant's suggestions for device development will be fed back to the manufacturers.

Five participants commented on the noise of the device but did not feel that this was a barrier to device use and in 3 cases felt that it was helping them sleep!

One participant mentioned that the device had an unpleasant smell when turned on the same participant reported that it generated heat.

Trial Processes

There were 2 comments made about trial processes. One participant requested the addition of reminders between visits to prompt participants to commence diary and peak flow data collection in the 2 weeks before a study visit and one participant requested increased contact between the trial team and participants between study visits.

Partner's Experience

Motivation

Both partners reported that they were happy for the device to be installed in their home because they were keen for anything that might lead to an improvement in their partner's asthma control.

Information

Both partners attended an information event and received information about the trial. Both felt that they had received adequate information.

Device Delivery / Installation

One partner reported that the bedroom had to be significantly modified in order to accommodate the device. The bed had to be completely re-orientated so that the device was not too close to a window.

Website

One partner had visited the website at the start of the trial but had not returned. The other participant had not had time to visit the website.

TLA Device

Both participants commented on the noise of the device. Both reported that it had been louder than they had expected having heard the device at the information event. Neither felt that the noise of the device was a barrier to its use.

Learning Points and Actions:

Categories	Learning Points & Actions
Motivation	*Learning Points:* 1. Different participants provided a number of different reasons for taking part in the trial. This shows that there are various different motivating factors for participation and these should be explored in all potential recruits. *Actions:* 1. We will use a selection of responses to update the frequently asked questions area of the trial website. "Why participate in the LASER Trial?" 2. Participant's responses will be used in the Information Event presentation to illustrate the possible benefits of trial participation to potential new participants.
Information Events	*Learning Points:* 1. Participants who were able to attend the Information Events gave positive feedback. Information was delivered in such a way that participants felt that they had been well informed before being asked to participate in the trial. 2. Participants enjoyed the opportunity to meet other potential participants and our PPI members, giving them the opportunity to discuss their condition and realise that they are not 'alone'. *Actions:* 1. New sites will be encouraged to hold information events to provide potential participants and their families with information about the trial. The trial team will support local centres in the set up and delivery of these events using the same format with representation from the trial team, local site teams and device manufacturers.
Participant Information Packs / PIS	*Learning Points:* 1. The Participant Information Sheet and Information Packs were

Participant Information Pack / PIS contd..	well received. Participants felt that the information delivered was adequate and pitched at an appropriate level. 2. The orientation of the device template is currently not clearly defined. *Actions:* 1. The device template will be modified to specify the orientation in which it should be used with respect to the participant's bed. This will require a minor ethics amendment as it will be issued to potential trial participants.
Trial Visits 1&2	*Learning Points:* 1. Some trial participants were surprised by how long their trial visits had taken. 2. Most participants find the trial paperwork straightforward and do not find the daily requirement for paperwork completion to be a burden. This may not be the case for all participants and clear explanation is required to ensure participants are aware of their responsibility to complete the paperwork for data completeness. *Actions:* 1. Future participants will be made aware of how long the study visits can take to make sure that they are aware that the visit may take up to 90 minutes in some cases. This will allow them to schedule the appointment without feeling pressured for time. 2. When introducing the trial and discussing what is required of participants, more emphasis will be put on detailing the daily requirement for diary completion and importance of the data collected for trial analysis. Most participants find that once in a routine that the paperwork does not take too long to complete but participants should be fully informed of their responsibilities so that they do not feel that the trial is adding additional burden. 3. Trial teams will be encouraged to re-assure participants before they fill in the questionnaires that there is some repetition in the questions but that this is necessary as each questionnaire is validated and analysed individually

Trial Visits 1&2 contd..	4. Trial teams should be available to answer participant's queries when filling in questionnaires at study visits to avoid missing data.
Device Delivery / Installation	*Learning Points:* 1. Some participants had to make modifications to their bedroom to accommodate the device. In most cases this was just the removal of a bedside table but in some, moving the bed or complete re-configuration of the bedroom was required to accommodate the device. 2. Some participants reported that the engineering team delivering the treatment device were inexperienced. This may impact on participant's confidence in the trial as a whole and there is a risk of devices being installed incorrectly if engineers are receiving inadequate training. *Actions:* 1. Participants are already issued with a device template so that they can see if the device can be accommodated in their room but, participants will be informed of the possible need for bedroom modification in order to accommodate the device before device delivery to ensure that they are happy with this if required. 2. Steps have been taken to ensure that future devices are delivered and installed by appropriately trained personnel. Bishopsgate will reduce the number of trained personnel able to deliver devices to maintain quality standards. Training for Bishopsgate personnel will be inspected and controlled by Airsonett, including an examination of competence before being added to the list of trained personnel authorised to deliver and install devices. Regular revalidation and re-appraisal will be implemented to ensure competences are maintained.
Trial Website	*Learning Points:* *1.* The website is currently under-used. Participants find the website provides useful information at the start of the trial but there is little return traffic.

Trial Website contd..	*Actions:* 2. The website is constantly evolving and we will continue to develop the different pages to make them as user friendly as possible and to attract interest in the trial. 3. Search Engine Optimisation (SEO) will be used to increase visibility of the trial website and to generate further interest in the trial. 4. Following the feedback received, we will develop the website forum – with input from our PPI members. Participants will be encouraged to visit the forum and comment on their experiences in the trial. 5. A participant newsletter will be issued quarterly to inform participants of trial progress. This will improve interaction with the trial team and allow us to highlight new developments within the website. Participants will be able to register to receive the newsletter via the website homepage.
The TLA Device	*Learning Points:* *1.* A number of important issues have been raised by participants that may impact on user experience and retention of participants in the trial. These include the noise, smell and heat generated by the device. *Actions:* 1. All user experiences and suggestions for development of the treatment device have been fed back to the device manufacturer, Airsonett. 2. Potential participants will be informed of participant's experiences and these issues will be included in the 'Frequently Asked Questions' area of the trial website and discussed at Information Events.
Trial Processes	*Learning Points:* *1.* Some participants feel that there is insufficient contact with the trial team between study visits.

Trial Processes contd..	*Actions:* 1. Trial teams will be encouraged to maintain contact with trial participants between visits. At a minimum trial teams will be asked to contact participants to remind them to start data collection 2 weeks prior to follow-up visits and to remind them about date and time of follow-up appointments.
Partner's Experience	*Learning Points:* 1. Participant's partner's experience of the treatment device and the trial processes are equally important to those of the trial participant's themselves. Being a treatment device that is installed in the patient's home, it is important that the device is acceptable to all, including partners and other family members. *Actions:* 1. Participants will be actively encouraged to invite their partners to the information events so that they can be informed of what trial participation involves and so that they have had the opportunity to see the treatment device before it is installed.

Qualitative Evaluation Research

Telephone Interviews

The research team designed a semi-structured telephone interview schedule (Appendix 1.) It was felt important to evaluate all of the different elements of the trial including the information events, the study visits, the installation process, the participant's experience of the treatment device and their experience of participating in the LASER trial. The telephone interview schedule was constructed with input from our PPI members.

WS conducted the qualitative telephone interviews. The first interview was supervised by AD, an experienced qualitative researcher from the University of Portsmouth. Using the interview schedule the researchers worked their way through the series of open-ended questions but at all times, interviewees were encouraged to express their own views in their own words. Each interview took between 30-50 minutes to complete depending on what the participant wanted to share with the researcher. Suggestions and prompts were used, as required, to help facilitate feedback from the interviewees. Audio recording of the interviews provided accurate verbatim transcripts. The telephone interviews were number coded and participants were assured that the information they were providing was strictly confidential.

Telephone interviews were transcribed verbatim by 'Way with Words' a secure online transcription service.

Response rates to the telephone interviews

All participants in the LASER trial were invited to participate in the telephone interviews. Participation in the interviews is optional. At the time of conducting the interviews, there were 25 participants in the trial and 17 that had completed at least 2 months in the trial. Of these 17, 13 consented to participate in the telephone interviews. 3 participant's partners had also consented to being contacted to take part in the telephone interviews.

Twelve were subsequently interviewed. Despite numerous attempts to contact them, we were unable to contact one participant and one partner to arrange an interview date.

Qualitative Data Analysis

The interview data analysis was guided by Framework analysis (Richards) as follows:

Step 1: Familiarisation with the data	Transcribed interviews were annotated with notes and memos by WS
Step 2: Construction of Initial set of categories	Construction of an initial set of identified categories.
Step 3: Refining and grouping together of categories	Categories were refined and grouped together by WS. AD independently read through a sample of the transcripts (P1, P4, P5, P8, P9, P10, P11, P12)
Stage 4: Constant Comparison	At this stage, consultation between WS and AD took place and final agreement reached.
Stage 5: Description of the findings and development of explanations,	Matrix developed by WS. Verbatim quotations from the interviews used, where appropriate to best illustrate the findings and to add “truth value” to the results

Findings

Notes on Interpreting the Findings

- The findings have been grouped in this report under general headings (Motivation for participation, Information Events, Participant Information Packs and PIS, Study Visits 1&2, Delivery and Installation, Website, the TLA device and LASER Trial processes). The presentation of the results reflects the order of the open ended questions of the interview schedule.

- Only participants who had completed at least 2 months of the LASER Trial were included in the telephone interviews so the participants had between 2 and 4 months of experience of the trial treatment device. It was felt that those who had been in the trial for less time would not necessarily be able to give a true reflection of experience of using the treatment device.

Respondents Characteristics

Ten female participants and 2 male partners were interviewed.

Trial Participants		**10**
	Male	0
	Female	10
	(Age range 20-66)	
Participant's Partners		**2**
	Male	2
	Female	0
		TOTAL 12

Detailed Findings Including Verbatim Quotations:

Motivation for Participation

All respondents were asked about their motivation for taking part in The LASER Trial.

A range of different responses were given by the participants. The most common reason given for participation was the opportunity to receive a treatment that would not otherwise be available to them.

Participants saw the trial as an opportunity to improve the control of their asthma and reduce the frequency of asthma exacerbations and unnecessary hospital admissions

… I think if there was anything that was going to help reduce my exacerbations, this gave me a huge incentive, because it is there to try and help reduce the exacerbations. ..(P4)

… if we can find new ways of preventing people having unnecessary hospital admissions and things like that…(P9)

One participant response highlighted the difficulty that patients with severe asthma face in the limitation of treatment options and desperation for new and improved treatment options in order to reduce the impact of severe asthma symptoms on daily life. The response was,

… when I was first approached to do the trial, I think I was at the stage where I would try anything. So, if anyone offered me anything, I'm more than willing to take part in it, because it's going to help me, at the end of the day. (P4)

Some respondents highlighted the perceived opportunity to reduce their medication burden and the frequency of courses of oral corticosteroids and their associated side effects

… Obviously I take a lot of drugs, and I feel that anything that would, not necessarily reduce the amount of drugs, but could potentially stop you having to take more drugs, would be a really good thing. (P1)

…my motivation was if this makes things more stable I may be able to reduce medication, that's my biggie. I thought if this makes a difference and I can reduce medication that ticks my box….(P6)

As well as recognising the opportunity for personal gain from the treatment, respondents highlighted the importance of researching new treatments for patients with severe asthma that will help other patients with severe asthma in the future.

…….I thought, well, I've had asthma all my life, so I don't mind being a guinea pig, if you know what I mean. Just try me out with any medicines or drugs now, because I'm in my 60s, and if that helps the children that are getting asthma now…. we've got to try and find a cure for it….We need to find something that's going to help these children. Because I wouldn't like them to go through what I went through as a child….(P2)

I don't mind signing up for any trials relating to asthma because I just think that you give something back now, and try out medicines and that, and it may prove beneficial in the future to other people. (P2)

Respondents also appeared to feel that they were able to give something back by agreeing to participate

… I promised that I'd help in any way I could. … I've learnt a lot, and you've probably learnt a lot from myself and other people that participate in them……(P8)

Some participants highlighted the benefits both to themselves and the researchers in finding newer treatment options for patients in the future.

… It doesn't make me feel so bad that I've got asthma now. I can help someone else who feels how I used to feel. (P5)

Another important motivation described by respondents was the opportunity to learn more about their condition.

... and it wasn't just a positive experience, it was an opportunity to learn more about asthma as well. (P1)

... it's not that you're given more information, but you can access the information in a different way, which can help you to understand it better.. (P1)

And for their condition to be monitored more closely,

….I thought if I was going to be monitored and checked on it might be beneficial to me as well as to whoever was collecting in the study. (P7)

One participant felt that participating in clinical trials and the associated increased contact with the research team had lead to improved asthma control through simple measures such as learning correct inhaler technique and the role of each of the various prescribed medications.

..it's quite good because not only do you get research but….., like I said, if I didn't take part in this trial I'd still be taking my blue inhaler wrong really. So it is pretty much give and take in the whole trial because we get up to date on our asthma to make sure we're all okay and you get to know how well this machine's doing….(P5)

The nature of the treatment device also played a part in motivating participants. One respondent identified the opportunity to participate in a trial that did not involve 'testing chemicals' was an influencing factor in the decision to participate.

… I'd heard of people trialling drugs which I always thought I'm not sure I would actually do that myself but this is completely different……it's not testing chemicals, as it were, or unknown. This is a different concept altogether…..(P6)

Another participant identified the simplicity of the trial as a reason to participate. The fact that the trial does not encroach on day to day life was seen as a positive factor in deciding whether to take part.

… if there's anything that I can do to help or ease [symptoms]…. it seems like a pretty innovative way of doing it, that doesn't really encroach on my daily life at all. It goes on when it goes on, and it turns off. So, it's a very easy thing to do, and the paperwork's really quick.(P10)

Learning Points:

1. Different participants provided a number of different reasons for taking part in the trial. This shows that there are various different motivating factors for participation and these should be explored in all potential recruits.

Actions:

1. We will use a selection of responses to update the frequently asked questions area of the trial website. "Why participate in the LASER Trial?"

2. Participant's responses will be used in the Information Event presentation to illustrate the possible benefits of trial participation to potential new participants.

Information Events

Information events were held at the start of the trial. Participants were invited to attend a meeting to discuss The LASER Trial and what would be involved if they did agree to participate.

The information event consisted of a number of presentations delivered by different members of The LASER Trial team. There was an introductory presentation about asthma and how the treatment might benefit patients with severe allergic asthma. This was followed by a presentation outlining the schedule of procedures and study visits. There was a live demonstration of the TLA device so that participants could see the device in action and then a question and answer session. The meeting was concluded with signposting to the website to allow participants to access further information. Participants were given an information pack including a Participant Information Sheet (PIS) to take away and read in their own time.

The response to the information events was very encouraging.

It was very useful. Obviously it was Prof Chauhan who led the one I went to. Yes, there was a lot of information given there, how to access information about it, as well, obviously going and actually seeing the machine, and in action, as well, and talking to all the different members of staff about asthma, and how they felt the trial was going to impact learning about asthma, as well..(P1)

I thought you'd covered all that I needed to know and I understood clearly what was happening and I knew that it, that would be followed up with hospital visits which have been very good…(P6)

the launch event was very informative as well; it was nice to be able to see the machine on display, and being talked through how it all worked. (P4)

….it gave a good overview of what was involved and how long it would be and all of the ins and outs. (P7)

Participants also described the benefit of meeting others with asthma and the realisation that they are not alone and, others in similar circumstances would also be participating in the trial.

…..and it's amazing how many people actually... You don't see a lot of people with asthma, I must admit. I don't know...actually, none of my friends have asthma. It's not until you get into a room with other people, and you start talking to them, that you realise how it affects them. (P4)

…it was good to see other people there as well who were taking part… (P6)

Three participants highlighted the importance of including relatives in the information events;

One attended the information event with her husband:

…being in the same room together, it affects both of us, so he needs to understand what impact it's going to have on our life, really. So, yes, it was good for him to see…(P4)

Another attended with her partner and her son:

…our family members could come along and see it, and look at it, and things like that. When you say a big machine's coming in to help mum breathe, it's a bit daunting on them, but once they saw it, both [Partner] and [Son] were, oh, is that it? (P10)

One participant found the information event particularly useful. She attended with her partner who was not able to access the information through reading the information sheet and she found that he was able to benefit from the information delivered by spoken presentation much more easily.

..and obviously he has trouble reading, so the talk probably helped him more than it did me. (P8)

Learning Points:

1. Participants who were able to attend the Information Events gave positive feedback. Information was delivered in such a way that participants felt that they had been well informed before being asked to participate in the trial.

2. Participants enjoyed the opportunity to meet other potential participants and our PPI members, giving them the opportunity to discuss their condition and realiase that they are not 'alone'.

Actions:

1. New sites will be encouraged to hold information events to provide potential participants and their families with information about the trial. The trial team will support local centres in the set up and delivery of these events using the same format with representation from the trial team, local site teams and device manufacturers.

Participant Information Pack & PIS

Participants who were able to attend the information event were given an information pack which included information about the trial, the PIS, a device template (footprint of the TLA device to check that the device would fit into their bedroom) and generic information about participating in clinical trials.

Generally participants felt that they were given sufficient information to make an informed decision about participation in the trial.

It was all good. When we finally said yes we were under no illusions or what it was going to be. (P8)

One particular aspect that participants found useful was the device template

….the template obviously shows you how big the machine is going to be, so you get a picture of how much of the room it's going to take up. (P5)

…One of the really useful things in there was the little maps telling how much it would take your room. That is a bit of a consideration. (P7)

One participant did highlight however a problem with the device template.

…the bit of paper was brilliant, but it didn't tell you that the machine had to be a certain way …I measured it the wrong way. It should have been the other way. (P10)

One participant stated that her husband had read the information pack and summarised the information for her. It is unclear whether this was because the information was not clear enough for her to understand.

I have to say, my husband read more than me, actually, [unclear] tell me the basics. He's more into the science bit. (P3)

Other participants also shared the information with their family members.

It was useful for me, but not just for me; my husband and my eldest daughter read it as well, because obviously, as I've said before, my eldest is quite concerned about my asthma, and she found it useful to read that as well. My husband was very supportive with it, and the information pack, I think, did help, because I'd had quite a lot of information beforehand, as well…… I didn't really have too many questions, but my family did, and it answered for them in a way that I couldn't answer for them….(P1)

Participants were asked specifically about the participant information sheet and whether this had answered all of their questions and was easy to understand.

the content of the information sheets were pretty easy to understand and what's going on, why it's happening….You have enough time and I was always told that I'm allowed to quit the trial whenever need be and I was always doubly told to make I was doubly sure…. I didn't feel pressured into signing or anything, but I knew what I was getting into and also I knew if I could get out of it, I could, yes….(P5)

I think everything that I needed to know was definitely there….(P2)

It was totally clear information… I think it was covered… as a patient, to a good level, really. Sometimes too many long words and things like that can be a bit overpowering, can't it? I think it was ideal for everyday people, and it was a good level…(P9)

It was good…you have a knowledge of certain words anyway, because we deal with it every day, day in, day out. So, they need to have something scientific in there, but also it needs to be understandable. So, no, I found it quite easy to understand…(P10)

…there is nothing that I wish I knew or tried out beforehand…(P7)

Participants generally felt that they were well informed and no participants felt that they had been given inadequate information or felt that they were pressurised to participate.

Learning Points:

1. The Participant Information Sheet and Information Packs were well received. Participants felt that the information delivered was adequate and pitched at an appropriate level.

2. The orientation of the device template is currently not clearly defined.

Actions:

1. The device template will be modified to specify the orientation in which it should be used with respect to the participant's bed. This will require a minor ethics amendment as it will be issued to potential trial participants.

Trial Visits 1 & 2 (Screening Period)

Participants who were interested in participating in The LASER Trial after attending an information event and / or reading the Participant Information Sheet were invited to attend their local recruiting centre for screening. Screening consisted of 2 hospital visits. The initial visit (Screening Visit 1) included consent, assessment of eligibility based on current available information, completion of a Case Record Form (CRF) including demographics, asthma history, past medical history and smoking history. Participants also completed a questionnaire (ACQ,) lung function tests, blood tests and allergy testing. Participants were issued with a peak flow meter for measuring their peak flow along with an asthma control diary for 2 weeks before their second visit (Randomisation Visit 2) where their results were assessed and their eligibility confirmed. Those that were eligible completed further baseline questionnaires and lung function tests before being randomised.

Participants were asked about these 2 initial study visits

Information:

Participants responded positively when asked about whether they felt that they were being kept informed and had the opportunity to ask questions.

…when I did come up for the first visit, everything was talked through again and re-explained…(P1)

…like I said, I was always asked to make sure if I understood everything (P5)

Length of Appointment:

Participants were asked about their experience of the length of the study visits. The responses were varied. Some participants found these visits to be as long as they had expected others felt that they took much longer.

Some participants were happy with the length of the visits and actually the visits were quicker than they had expected.

Yes, well, actually they didn't take as long as I had expected. I thought they would be quite a bit longer, but no, they were fairly quick…(P1)

…they weren't too short and they didn't take forever and…time wise it was absolutely spot-on I would reckon, yes, definitely. (P5)

No, they were very good. They made the appointment, I wasn't kept waiting, I went in, it was only about half an hour, so it was really good. (P2)

I think it was about the length that I expected. I was just really happy to be accepted, to be honest (P4)

No, I think I don't remember thinking, oh God, this is going on too long. You know what it's like, oh come on, wind it up. No, I didn't. And I felt that all the tests were well explained and so that's absolutely fine. (P8)

Other participants recognised that the visits might take some time with the amount of paperwork and number of procedures to get through.

No that was fine. I knew there would be a lot of boxes to tick. (P7)

Three respondents were surprised by how long the visits took.

I think the first one, the introductory, doing all the paperwork, doing an order checklist, that took longer than I expected…. If I was told it was going to take two hours, then I would have made sure I'd made it for two hours…..it took almost that long, the first one, when I'd finally done all the paperwork and questionnaires. (P9)

….. I think the nurse said it would take about an hour and 15 minutes, but it took a bit longer. (P9)

I think it was about an hour and a half, which wasn't a problem. I was just a bit, oh, okay.(P10)

One participant had a particularly long visit for reasons unknown. She commented that the staff were also new to the paperwork and procedures and that the subsequent visits had been better

The first one was. At the first initial visit, we signed all the papers and the books. That was horrendous. I think I was over there three and something hours. ….. I suppose the nurses and doctors, like yourself, are all new to this. The initial bit is going to be long and I expected it to be long, but as you go through the trial and you return, the visits, it's getting quicker and quicker….(P8)

It is likely that this was one of the early study participants.

<u>Procedures:</u>

All respondents were happy with the procedures that were asked of them during the study visits including lung function tests, allergy tests and blood tests. These patients are familiar

with these tests from their normal clinical care and so had a good understanding of what was required before agreeing to participate in The LASER Trial.

I've done those tests, most of those tests in the past and they're all pretty easy to understand. I was even explained what each one was testing for and stuff, so it was pretty… yes, really good. (P5)

Yes, breathing tests, allergy testing, it was all what I expected to take place, but I mean, all of that was spoken about in the training meeting. So, I think, you knew what you were letting yourself in for beforehand anyway. You knew you were going to have blood taken, and...(P1)

Paperwork:

Throughout the trial, participants are required to complete various diaries and questionnaires for later analysis of endpoints. Participants complete a daily 'LASER Diary' which records device use (Yes or No and number of hours used), Additional hours of device use (Yes or No and number of hours used), Time off work or study (Yes or No and hours off) and whether they are currently taking oral corticosteroid tablets (Yes or No and dose.) Participants also collect Peak Flow readings and an Asthma Control Diary for 2 weeks prior to each follow up visit and are asked to complete and Exacerbation diary at the onset of an asthma exacerbation throughout the trial. In addition to this participants are issued with a Resource Use Log to document visits to healthcare professionals during the trial as part of the health economics evaluation.

The participant's experience of the trial paperwork was on the whole positive. Most participants found the paperwork easy to complete and did not find it to be a burden.

I've found them really easy to actually get into. I have them by my beside, so the first thing I do in the morning is fill in my diaries…the LASER, it has a shelf and that's where all my paperwork sits, and so it's the first thing I do when I wake up in the morning…..(P4)

I'm absolutely fine with what I've got to fill in. It's ever so self-explanatory. Not hard to fill in, really. It's just a couple of circles, and a couple of numbers to put in each time. (P10)

it's self-explanatory. I didn't find it too difficult. I just...because you have to do your peak flow, I just got out of bed and did that straight away in the morning. I left it next to the bed so that you never forgot about it. You just did it straight away. I didn't think it was too much to do. It only took a minute in the morning and the evening to actually do, so it wasn't a lot to get done, and it certainly wasn't difficult to fill in…(P1)

…the daily one is really easy and to be honest I could fill it in every couple of days and just work how long each night I was under it. It is really quick and easy to fill in. The two week one was quite hard to remember not to take my inhaler as soon as I woke up but to do the Peak Flow first….(P7)

One participant appeared to find the completion of paperwork to be particularly burdensome.

…Trying to remember to put down when you've got the doctor's. If we're going to be honest, I try not to go because I haven't got to worry about filling that out then. The diary is okay. I do an average now of when I'm on the machine, because I'm up and down through the night, but not through my asthma. I'm up and down so I do an average of being under the machine. And what's the other one? I can't remember now, and I was buggered if I'm going to have an exacerbation period where I've got to come over and see someone, I'll avoid that as much as I can. (P8)

Of particular concern is the fact that she states that she would alter her behaviour so as not to have to complete the paperwork. Obviously this would be a concern for the trial in terms of data collection. It is important that we emphasise the importance of the trial paperwork in terms of collecting reliable data for the trial analysis.

Questionnaires:

The trial team are conscious that there are a significant number of questionnaires that participants are being asked to complete. (7 questionnaires completed by participants at different time points and 2 completed by carers.) Pleasingly, most participants found questionnaire completion easy and recognised that if they had a question about any of the questionnaires, there was somebody available to ask for help.

….everyone has their own style of doing questionnaires and stuff. But even if I did have a problem with anything it's so easy to get an answer quickly (P5)

…It's all very clear on the sheets what you have to do, and it's all explained to you as well, while you're doing it, so no problem there at all. (P1)

…Sometimes, I was dubious where you had to tick, on some bits, but then once [Research Nurse] explained why it needs to go here and there, I was okay…(P10)

...I found them quite easy to fill in. (P2)

…they're all straightforward (P4)

Two participants felt that there was repetition in the questions and that this was confusing.

No, I thought there were some questions that were asking the same thing and I thought are they trying to catch me out… (P3)

Learning Points:

1. Some trial participants were surprised by how long their trial visits had taken.

2. Most participants find the trial paperwork straightforward and do not find the daily requirement for paperwork completion to be a burden. This may not be the case for all participants and clear explanation is required to ensure participants are aware of their responsibility to complete the paperwork for data completeness.

Actions:

1. Future participants will be made aware of how long the study visits can take to make sure that they are aware that the visit may take up to 90 minutes in some cases. This will allow them to schedule the appointment without feeling pressured for time.

2. When introducing the trial and discussing what is required of participants, more emphasis will be put on detailing the daily requirement for diary completion and importance of the data collected for trial analysis. Most participants find that once in a routine that the paperwork does not take too long to complete but participants should be fully informed of their responsibilities so that they do not feel that the trial is adding additional burden.

3. Trial teams will be encouraged to re-assure participants before they fill in the questionnaires that there is some repetition in the questions but that this is necessary as each questionnaire is validated and analysed individually

4. Trial teams should be available to answer participant's queries when filling in questionnaires at study visits to avoid missing data.

Device Delivery and Installation

Following randomisation, participants are contacted within 72hrs by Bishopsgate, a third party engineering company, contracted by Airsonett to deliver and install trial devices. Device installation is expected to occur within 10 working days of randomisation.

On the whole, participants' experience of the device delivery and instalment process has been positive. There were many good experiences and most participants felt that the process was smooth and hassle free.

…… Everything went pretty smoothly actually…. and they explained everything, what I need to know about the device and how it turns off. They asked me what time I go to bed to make it activate and then obviously deactivate when I wake up. Yes, it went really smoothly actually. Yes. (P5)

Participants reported that they were contacted shortly after randomisation and the company were able to arrange a convenient time for delivery. The company were also accommodating if the participant was not ready to receive the device and were prepared to wait.

... they phoned me up, told me the days they were going to be in the area, and said, we've got these time slots, which one suits? And then they phoned me up when they were about an hour away, and said they're going to be there in about an hour, and they were lovely (P1)

…They contacted me within a couple of hours, and they fitted it in around me. They told me when they were going to come. I had a call about 20 minutes beforehand I think it was, to make sure that I was home…(P10)

….They arrived on time, the right day…(P5)

… They phoned me to tell me they were on their way. They weren't at the house long, …(P4)

… I had the time and they turned up on time….(P3)

… and they phoned me about an hour before to say that we're coming to yours now. Don't worry about it if you're not there, we'll wait. So that was fine….(P9)

Across the board, participants reported that the delivery staff were polite and friendly.

… Yes, and very polite and, yes, very friendly actually. (P5)

… Very nice guys …(P6)

… they were absolutely brilliant..(P1)

… They were brilliant…(P10)

The delivery team have a checklist to follow to ensure devices are installed correctly and that participants are given instructions for use. Participants found that this was helpful and felt confident that they had received adequate instruction by the time the delivery team had finished.

… they measured distances; they said, don't have that window open, but you can open that one …it was quite a comprehensive lesson. I could probably build one now…(P1)

… They came in and set it all up, showed me how it worked.…… they went through all the menus with me and everything …… They were so good, they went through everything with me, showed me how it all worked and what each menu did…(P2)

…. ***they installed it pretty quickly, but then they explained how it all worked, and then set the timer in it for me so that I didn't have to worry about that, and then left me with the instruction booklet…(P4)***

they were very clear about how everything worked and I wanted them to program it to come on automatically which they said yes to…(P7)

… I'm not technical at all, I can't set up anything, me, and this was quite easy to look at and say, oh, yes, I'll press that one, and then there's not a lot of buttons on it that can go wrong anyway…(P10)

Some participants reported that the process was quicker than expected.

… that all went very smoothly, took a lot less time than I thought and they were here. Very nice guys, so that's good…(P6)

…… Yes that was done efficiently and quickly.…(P7)

…they took about 15, 20 minutes to set it all up, and off they poodled…(P10)

Participants were pleased that the company cleared up after themselves and disposed of the packaging.

… They took all of their boxes and rubbish away and things …(P7)

… No, they were very nice and very quick and didn't make a mess…(P3)

Bedroom Modification:

Participants were asked if they had had to make any modifications to their bedroom to accommodate the device. Trial participants were given a device footprint 'template' in their information pack so that they were aware of the size of the device and could check that their bedroom would accommodate the device beforehand.

Two participants reported that they had to move their bedside table and one, their make-up table. Three participants had to move their bed to accommodate the device. Participants seemed happy to make these modifications so that they were able to participate and did not feel that it was a barrier to participation.

… I removed my bedside table, but that's not a great hardship. It didn't really have anything in it that needed to be there…(P1)

…. My bedside locker just went across a bit and it's sat next to the bed…(P2)

…I lost my makeup table, but hey….(P8)

All we had to do was I had a bedside table, which I exchanged for the glorious device, but nothing else… I think it's just an acceptance, if you want to try and make things better for yourself then there's going to be a trade off and the trade off is the coffee goes on the floor. It's no big deal really….(P6)

…..it did just fit into my bedroom because I've got a one-bedroom flat, but it's more of a rabbit hutch. But I have moved my room around purely… it does fit better now I've moved my room around….. in the information pack there was a bit of paper you could pull out and it showed how big it was and obviously that fit and it was all correct…..(P5)

…I've got a bay window and my bed's in the bay window, and I just had to move it forward slightly, that's all…(P9)

One participant had to modify her bedroom to accommodate the device and the delivery team helped her move her bed.

…because I'd measured it the wrong way, I didn't have enough room, and so, they helped me move bits… It was just so that we could open my door slightly a bit more, because instead of it being one way, it was the other way, and they just pushed the bed over a bit more, and it was okay… (P10)

To date, no participants have been excluded from the trial because their bedroom cannot accommodate the device.

<u>Delivery Staff Experience:</u>

Of concern, there were 2 participants who reported that the staff did not appear to be familiar with the delivery and installation process. In one situation, the participant reports that the delivery team did not appear to know what they were doing.

… To be honest, they didn't 100% know what they were doing, in a way. One bloke was definitely a new person, and was shadowing somebody, and the other bloke, I think, had only done one machine before, if I remember rightly. So that was a bit… They knew how to put the machines together, but the man who did it, setting it up, was double-checking a lot. He was going through all the paperwork again and then checking it, and then going through the paperwork again. It was, obviously, very new to him.…(P9)

To a degree this is understandable given that these were the first participants in the trial and as further participants are enrolled, it is likely that the delivery personnel will be more familiar with the processes involved.

In another case, and more concerning, the participant reports that the device was assembled incorrectly and that it was only when she intervened that the device was then assembled correctly.

… I have to say the only snag, and it quite amused me, there were a couple of lovely chaps and I think they were like ordinary delivery, like they'd deliver a cooker or something, they'd been on the laser course and how to put it together. And so one was reading the instructions and one was putting it together. Then they had trouble putting the glass tray [unclear] and so I came up to give them another cup of tea and I looked at it and I had my folder and I said guys I don't want to say anything but I think you've got it round the wrong way! And they had put the bulk, the case, it sort of looks away from the bed, and they had

it where it was the other way around and they couldn't work out how to get the filter right over the bed because this was in the way. I said I think looking at this picture you want to turn it around. They went, oh yes, that's what it is… (P3)

We are aware of other situations where this has occurred and measures have been taken to ensure that devices are assembled correctly in the future. Further training has taken place and measures have been implemented to reduce the risk of further similar events in the future.

Learning Points:

1. Some participants had to make modifications to their bedroom to accommodate the device. In most cases this was just the removal of a bedside table but in some, moving the bed or complete re-configuration of the bedroom was required to accommodate the device.

2. Some participants reported that the engineering team delivering the treatment device were inexperienced. This may impact on participant's confidence in the trial as a whole and there is a risk of devices being installed incorrectly if engineers are receiving inadequate training.

Actions:

1. Participants are already issued with a device template so that they can see if the device can be accommodated in their room but, participants will be informed of the possible need for bedroom modification in order to accommodate the device before device delivery to ensure that they are happy with this if required.

2. Steps have been taken to ensure that future devices are delivered and installed by appropriately trained personnel. Bishopsgate will reduce the number of trained personnel able to deliver devices to maintain quality standards. Training for Bishopsgate personnel will be inspected and controlled by Airsonett, including an examination of competence before being added to the list of trained personnel authorised to deliver and install devices. Regular revalidation and re-appraisal will be implemented to ensure competences are maintained.

Website

The LASER Trial website has been developed with input from our patient representatives to be an information resource for trial participants as well as for healthcare professionals.

The website has various pages displaying trial information, recruitment updates, links to partner organisations and asthma charities and a page where people can register their interest in participating.

The website links to the trial Facebook page and Twitter account and there is a twitter feed displaying the recent Twitter activity.

One area of the website which we felt would be particularly useful for participants was a forum where participants could discuss the trial and their experiences. This would be useful for both current participants and also those interested in participating. Unfortunately, there has been little activity on this page and this remains an under-used resource.

2 participants commented that they would like a forum for participants to discuss their experiences.

….. I just felt that it would be quite good to have more of people chatting on there about their experiences, how it's working, again, what sort of impact it's having on family, and things like that….(P1)

….. It might be interesting to see what other people's comments are on there. ..(P7)

Some participants had not been to the website,

I haven't actually. I must admit, I haven't…(P4)

…you spoke about it, but I haven't managed to get on there and have a look...(P10)

One was not aware of the website at all

I don't think that's been mentioned to me, actually…(P9)

As with any website, it is important to generate interest so that people return to look at the site after their initial visit. It appears that in most cases participants visit the website, review the information and then do not return.

….. To start with I did, but I haven't lately… (P8)

….. I did at the very beginning… I had a quick read through to just make sure I was aware of what was on there….(P7)

I did, way back, but not since, I can't remember much about it to be honest… I just didn't feel the need really, I had all the information that I felt I needed…(P6).

….. I went on it right at the beginning and saw that more people had joined but I had to say I haven't been back on it for a couple of months now…(P3)

Learning Points:

1. The website is currently under-used. Participants find the website provides useful information at the start of the trial but there is little return traffic.

Actions:

1. The website is constantly evolving and we will continue to develop the different pages to make them as user friendly as possible and to attract interest in the trial.

2. Search Engine Optimisation (SEO) will be used to increase visibility of the trial website and to generate further interest in the trial.

3. Following the feedback received, we will develop the website forum – with input from our PPI members. Participants will be encouraged to visit the forum and comment on their experiences in the trial.

4. A participant newsletter will be issued quarterly to inform participants of trial progress. This will improve interaction with the trial team and allow us to highlight new developments within the website. Participants will be able to register to receive the newsletter via the website homepage.

The TLA Device

Participants were asked if there were any changes to the device or modifications that they would like to make to improve the device for future users.

In general, participants' experience of the device was positive.

General Appearance

5 participants commented on the appearance of the device.

…. it looks quite cool. [Unclear] it did look cool for me because I like all the sci-fi stuff….It does look a bit like War of the Worlds. [Unclear] but, yes, it's not loud, it's not an eyesore. I find it quite cool really….(P5)

….the little 'uns, when they come in, they think, wow, what's that? It's a spaceship over your bed…..But, I think, essentially, aesthetically it's not very unattractive; it's quite streamlined and modern looking. There's nothing to dislike about it, what it looks like….(P1)

…I quite like it. I do like it. I think, like I said, I will miss it when it goes….(P8)

One participant commented on the shelf and felt that this was a useful design feature given that it had taken the place of the bedside table.

I really like the glass shelf on it; that is really handy because it is in place of my bedside table and being able to put a few things on there is nice…(P7)

One patient commented on the appearance of the device. She reflected on the appearance in relation to starting a new relationship and having to explain to a new partner what the device was and why she had it in her bedroom.

…and on a relationship, I mean, it didn't affect me this time around, because my relationship broke down anyway and that was just before the trial started… but that is a thing that does worry me a little bit, if I do meet a new person and I'm going to have to introduce the machine, that's a bit embarrassing. That's one thing that, well, it doesn't worry me, it concerns me a little bit….(P9)

Changes to the Device

Most participants commented on changes they would like to make to the device.

A number felt that the device was bulky, taking up a lot of space and intruding on their personal space. Some of the participants felt that a smaller device that was more portable might be useful as they would be able to use it when on holiday or staying away from home. A portable device might also be used in the participants' living room as well as the bedroom.

….Apart from making it slightly smaller... To be honest, I think the device is absolutely fine. I mean, it is large, obviously, but I suppose with all of the filters in, it serves a purpose….(P1)

…If it was portable, obviously, yes, that would be an option. Yes, that would be quite a good idea….(P1)

Well, obviously, it is pretty big. The base of it is pretty big. It does take up a lot of room……, it'd be quite handy to have a portable device, I guess…. if I was to go away, you could...something you could take with you would be handy…(P4)

One participant suggested making the device wall mounted to take up less space.

I'd make it a little bit less bulky. It's a little bit intimidating, if you know what I mean. You've got these big machines hovering over your bed, and it's from the base to quite a bit over the top of your bed. So I think I would make… if there was a way of making that slightly smaller or changing the design, that maybe it's wall mounted thing, so it didn't take up quite so much space…(P9)

Another participant suggested that the neck of the device could be adapted so that it was able to swivel out of the way.

…the bit that comes up and over isn't moveable. It's a stationary piece of apparatus. If you could move that, and have it so that it's moveable, that would be fantastic…, it could be put out of the way, and if my son uses my bed as a trampoline, then he doesn't have to watch out for my machine. Just silly things like that, which is the normal day to day use of a bed!...as well, making the bed it makes it bloody awkward. .(P10)

Some participants mentioned the shelf on the device.

Two participants felt that this could be slightly larger to accommodate what would otherwise be stored on a bedside table.

I think the only thing I would say, I would like a slightly larger bedside table bit on the side……Yes, because by the time you've got your clock on there, and a glass of water, night-time inhaler, things like that...(P1)

it's not really a problem but it's a bit more of an annoyance really, where the bedside table which is an absolutely awesome idea but it's not big enough for me, for my medication that I like to have on top of it…(P5)

Another participant felt that the shelf was too small and that they were worried that they might spill coffee into the device if they used it as a bedside table.

….there isn't room on that little table thing, if that's what it is, but I would never put anything on there anyway for fear of spilling. The only thing I would put on a bedside table really would be a cup of coffee in the morning… I think it's just an acceptance, if you want to try and make things better for yourself then there's going to be a trade off and the trade off is the coffee goes on the floor. It's no big deal really…(P6)

<u>Problems with the device</u>

There were 5 specific problems identified with the treatment device.

Three of these problems relate to user experience - Noise, Smell and Heat generated by the device.

Noise:

A number of participants commented on the noise of the device.

Most participants felt that the noise level was tolerable. No participants felt that the noise was a barrier to device use.

Noise level is absolutely fine…(P1)

You can hardly hear it…, it's quite quiet…(P2).

Two participants were surprised by the noise of the device having heard it at the information event. At the information events, due to the background noise and hotel air-conditioning it may have given a false representation of the noise level of the device. In neither case did the noise impact on the participant's use of the device.

…..when I saw the device at the hotel there appeared to be no noise at all but there is. And when I first heard that I thought that is going to keep me awake or it's going to keep me awake for a fortnight until I get used to it. And we both felt the same….(P6)

I think when you go to the information event, because obviously there were a lot of people in the room and the machine was on – one thing my partner asked was, how noisy is it? And the machine was on at the time and it's not until it's actually installed in your house and you actually go into the bedroom for the first time, you hear the noise. It's not an annoying noise. It sounds like an air-conditioning unit, I guess, but you get used to it..(P4)

Three participants actually felt that the noise of the device was helping them to sleep!

But actually it had the opposite effect. And we actually quite like it…. we have both said we have slept better with the device and that's [partner's name] as well. Whether that's the noise or whether it's doing its stuff we don't know. (P6)

Sometimes, I think, the noise helps you sleep…… it's kind of a constant noise, rather than being a...there's no wave to it, so because it's a...it then ends up just blending into the background noise…(P4)

It just vibrates when you first put it on, and that's it, and then it's a lovely, soothing... I just drift off to sleep with it… Because I know I can get to sleep with it. I'm going to miss it when it goes….(P8)

Asked how she would describe the noise to a potential new participant in the trial, one participant responded:

….I would say it's more like an air conditioning, like when you're abroad and you've got the air conditioning on low, that sort of deep hum, it's constant and just there rather than annoying, that's what I would say….(P6)

Another participant said,

It's almost like if you have a Virgin Box or a Sky Box in your bedroom – that makes a noise, as well. So, I think, it's just you getting used to the noise, that's all it is… (P4).

Smell:

Only one participant commented on the smell generated by the device,

It smells bloody awful when you switch it on; absolutely awful….., when you switch it on, it makes that vibrating noise and you can smell it, so what I normally do is now it comes on and then I'm either asleep when it comes on because it's on automatic, or if I come to bed early, I might switch it on and then go to have a wash or bath, and then when I come back it doesn't smell horrible….(P8)

Heat:

The same participant also commented on the heat generated by the device,

..it kicks out a lot of heat as well….(P8)

No other participants mentioned the smell or heat generated by the device.

Other Problems:

Three participants mentioned the device's 'airshower'. It is made of a coarse material which is quite abrasive. 2 participants commented that they had hit their head on the device and one that she had got her hair tangled in the 'airshower.'

…when my toddler climbs in with me and I sit up and bash my head on it…(P1)

…also, the shell of it underneath, it looks very soft. It looks quite foamy, but it's very coarse. I have actually hit my head on it a few times, and I have managed to actually scrape my hand on it. But, yes, it takes a bit of getting used to, I think, getting out of bed and having to duck to get out, and to get back in again. It's just remembering that it's there …(P4)

…So when I sit up sometimes, if I forget, I get my hair tangled in it…(P2)

…You hit your head on it all the time, which is what I keep doing …At first it was because you're not used to it being there, and then you're used to it being there, so you're trying to move out of the way of it … You can't help but bash your head on it really when there's a great big thing a foot away from your head…(P10).

One participant had a problem with the electrical plug,

…the main problem that I've had is the three-pronged plug keeps coming out of the device occasionally….a simple knock or even sometimes for some reason just suddenly decides to fall out of place. The first two nights I had it, it actually wasn't on because it actually fell out….(P5)

This is a worry if participants are not aware that the plug has become disconnected. Hopefully the lack of sound and visual display on the device's monitor would alert them that there was a technical issue and the participant could then contact their local trial team to investigate.

Learning Points:

1. A number of important issues have been raised by participants that may impact on user experience and retention of participants in the trial. These include the noise, smell and heat generated by the device.

Actions:

1. All user experiences and suggestions for development of the treatment device have been fed back to the device manufacturer, Airsonett.

2. Potential participants will be informed of participant's experiences and these issues will be included in the 'Frequently Asked Questions' area of the trial website and discussed at Information Events.

The LASER Trial Processes

At the end of the interview, all participants were asked if they had any suggestions for improving the service or anything additional that they wanted to add.

...a reminder about the, because you have to keep your readings, the peak flow diary, two weeks before you go in and test, so if we could be reminded about that. I know I should work it out myself and put it in my diary but...(P5)

One participant had felt that the lack of contact between the 2nd and 3rd visits was a problem and that it would be nice to have contact to check that everything was running smoothly.

so far, it's been pretty good. I think actually more communication with the [unclear] that's running it would be good. I've found that you've done your first trial…. you've been put onto the programme, and then it's going to be installed, and then you're left for three months. It would be good to just have a check-up call – is it installed? How's it going? Anything you're worried about, type call, just a little check to make sure…(P1)

In actual fact, there is a 1 month telephone review scheduled into the trial, included for this exact reason. It is unclear why in this particular case the telephone review did not happen.

Learning Points:

1. Some participants feel that there is insufficient contact with the trial team between study visits.

Actions:

1. Trial teams will be encouraged to maintain contact with trial participants between visits. At a minimum trial teams will be asked to contact participants to remind them to start data collection 2 weeks prior to follow-up visits and to remind them about date and time of follow-up appointments.

Partner's Experience

Motivation

Both partners reported that they were happy for the device to be installed in their home because they were keen for anything that might lead to an improvement in their partner's asthma control.

If it's going to do [Participant's Name] good, then I'm all for it. (1)

if it's someone's health you're going to do whatever it takes to try and make it a bit more comfortable for whoever, aren't you?...(2)

One participant described the team approach between him and his partner in terms of trying to achieve the same goal of improving asthma control.

…I think anything which was going to, potentially, have a positive effect on asthma, I would have been interested… If I'd known about it and [Participant's Name] hadn't, I would have dragged her along to it, because obviously we've both got the same goal of getting better…(1)

Information

Both partners attended an information event and received information about the trial. Both felt that they had received adequate information.

Device Delivery / Installation

One partner reported that the bedroom had to be significantly modified in order to accommodate the device. The bed had to be completely re-orientated so that the device was not too close to a window. Despite this, he felt happy for his partner to participate if it lead to an improvement in her asthma control.

...I'm sure anyone's willing to sacrifice swapping things round to make it better for the person with asthma...(2)

Website

One partner had visited the website at the start of the trial but had not returned, he did not have any suggestions for improvements that would enhance user experience. The other partner had not had time to visit the website.

TLA Device

Both participants commented on the noise of the device. One partner reported that it had been louder than they had expected having heard the device at the information event. Neither felt that the noise of the device was a barrier to its use.

…after a while you do just get used to the slight noise it does make…it's just there. I suppose it's just like a piece of furniture; you don't take a lot of notice of it, it's just there…(2)

The machine they had running at that information event was quieter than the ones they actually got…
…but the machine's not that noisy, to tell the truth, it's just like an air conditioning unit. I'm quite used to that sort of sound, anyway...(1)

When asked about potential modifications to the device, one partner suggested incorporating a light into the device as the device had taken the place of their bedside table including the bedside lamp.

I suppose you could have something like a built-in light on it, or something like that…(1)

The same partner also suggested making the device portable.

it could be made smaller and more portable, then you could not just have it over your bed, you could have it over your sofa in the lounge…(1)

The other partner suggested increasing the size of the table.

The only thing I suppose, really, is possibly the shelf could do with being slightly larger…(2)

Learning Points:

1. Participant's partner's experience of the treatment device and the trial processes are equally important to those of the trial participant's themselves.
   Being a treatment device that is installed in the patient's home, it is important that the device is acceptable to all, including partners and other family members.

Actions:

1. Participants will be actively encouraged to invite their partners to the information events so that they can be informed of what trial participation involves and so that they have had the opportunity to see the treatment device before it is installed.

Discussion

Determining rigour and reliability in qualitative research has long been a contestable area. We have attempted to provide transparency by outlining how the interviews were conducted, details of participants taking part, audit trail of data collection and analysis (audio recording, verbatim transcriptions and interview quotations so that the words of the participants can be read, independent reading of a sample of verbatim transcriptions and consensus agreement) to provide the major considerations of trustworthiness, transferability, reflexivity and reliability

Conducting early qualitative evaluation (during the first four months) as part of a larger experimental study has provided us with an opportunity to address different questions (What is happening? How is it happening?) than otherwise would be possible with quantitative data collection alone. We have been able to “hear the voices” of the early trial participants, and their partners, to provide meaningful feedback to develop and enhance the subsequent trial processes and recruitment. Our experience from conducting this qualitative evaluation is that, although time consuming, the qualitative interviews and subsequent analysis have provided a useful insight into the difficulties, albeit minor at times, that patients and their partners have experienced and which are important to them. As a result we have a better understanding which has resulted in an informed plan of how to address these learning points with suitable actions to enhance the experience of taking part in the LASER Trial for future participants.

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- The LASER Trial PPI members for their input into the development of the telephone interview schedule

- All of the participants who took part in the telephone interviews.

RESEARCH TEAM

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Researchers:	Dr. Will Storrar, Clinical Research Fellow, The LASER Trial Coordinator
Report written by:	Dr. Will Storrar Dr. Ann Dewey

Appendix 1: Qualitative Telephone Interview Schedule

Qualitative Telephone Interview Schedule

(Participant – Pilot Phase)

A Qualitative Study to Explore the Use of Temperature Controlled Laminar Airflow (TLA) in the Treatment of Severe Asthma and Participant's Experience of Taking Part in the LASER Trial

Participant Identification Number	_____
Date of Interview	_____
Time of Interview	_____
Interviewer	**Name_____No._____**
Qualitative Patient Information Sheet (Version_____Date_____)	**YES □ NO□**
Consent Form Signed (Version_____Date_____)	**YES □ NO□**
Test Recording Equipment	**YES □ NO□**
Verbal Confirmation of Participant Consent	**YES □ NO□**
Verbal Explanation of Qualitative Study before starting interview	**YES □ NO□**
Check Participant ready to start interview	**YES □ NO□**

This is a brief overview of the topics to be considered. It is likely that the content of the interview schedule will develop and may incorporate other areas as the researcher reflects on each interview as it takes place.

The 'Prompts/Explore' sections in *italics* will only be raised if not covered spontaneously by participants.

TOPIC AREA 1 – Information Events

Did you receive adequate information about taking part in the trial?

Prompts / Explore: *Were you able to attend an Information Event?*

Was the information Event useful?

Was the Patient Information Pack useful?

TOPIC AREA 2 – PIS / Consent

Were the information sheet and consent form helpful and did they answer your questions about the trial?

Prompts / Explore *Was the Patient Information Sheet easy to read?*

Were you given adequate time to read the PIS before signing consent?

TOPIC AREA 3 – Early Study Visits

How did you find the first 2 study visits (Screening / Randomisation)?

Prompts / Explore *Did the visits take any longer than you had expected?*

Were there any problems with any of the tests or procedures?

Did you have any problems completing the questionnaires?

TOPIC AREA 4 – Trial Paperwork

Have you had any difficulty completing the trial paperwork?

Prompts / Explore *Questionnaires?*

The LASER Diary?

Asthma Control Diary (+Peak Flow recording)?

The Exacerbation Diary

TOPIC AREA 5 – Device Installation

Were there any problems with installing the device?

Prompts / Explore *Was the device delivered at a convenient time?*

Were the engineering team helpful?

Was any bedroom modification necessary to accommodate the device?

Did you receive adequate instructions on using the device?

TOPIC AREA 6 – Device Usage

Have you had any problems with using the device?

Prompts / Explore *Is there anything stopping you from using the device?*

Have you encountered any technical problems?

TOPIC AREA 7 – LASER Trial Website

Have you visited the LASER trial website

Prompts / Explore *Have you found the website useful?*

Is there anything that you think would be helpful to see on the website?

TOPIC AREA 8 – General (Trial) Comments

Do you have any suggestions on how the trial might be improved for future participants?

TOPIC AREA 9 – General (Device) Comments

Do you have any suggestions on how the device might be improved for future users?

TOPIC AREA 10 – Any other comments?

Is there anything else that you would like to say or comment on?

Thank Participant for taking part in the Qualitative Interview
Assure participant of confidentiality of responses
Switch off recording device

Appendix 2: Contribution to Content

Participant	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10
Motivation	■	■		■	■	■	■	■	■	■
Information Events	■			■		■	■	■		■
Information Pack / PIS										
Information Pack	■		■		■		■	■		■
PIS		■			■		■		■	■
Study Visits 1 & 2										
Information	■				■					
Length	■	■		■	■		■	■	■	■
Procedures	■				■					
Paperwork	■			■			■	■		■
Questionnaires	■	■	■	■	■					■
Device Delivery / Installation										
Delivery/Installation	■	■	■	■	■	■	■		■	■
Modification of Room	■	■			■	■		■	■	■
Website	■		■	■		■	■	■	■	■
TLA Device										
Appearance	■				■		■	■	■	
Changes to Device	■			■	■	■			■	■
Problems with Device										
Noise	■	■		■		■		■		
Smell								■		
Heat								■		
Other	■	■		■	■					■
Trial Processes	■				■					