Title

Acceptability of a theory-based adherence intervention for adults with asthma – a person-based approach

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Abstract

Objective: Nonadherence to inhaled corticosteroids contributes to poor asthma control. This study evaluated two different theory-based intervention approaches to address nonadherence in adults with asthma using a person-based, qualitative approach to investigate comprehensibility, coherence and acceptability.

Methods: The two intervention approaches addressed treatment beliefs and misconceptions in asthma, aiming to provide a common-sense rationale for medication adherence. Approach one reframed asthma using a concept of balance, the second approach was more traditional presenting medical consequences of nonadherence. We ran three focus group interviews involving 19 adults with asthma to investigate patient acceptability of the intervention approaches and their influence on perceptions of asthma and medication.

Results: Approach one was perceived as novel compared to current practice, logical and easily understandable. Its use of non-medical jargon was perceived as representing information more positively, moving away from stigmatizing people with asthma. Approach two was perceived as not sufficiently novel, not applicable to everyone's illness experience and triggering fear.

Conclusions: Patient feedback allowed us to refine our intervention strategy prior to running costly feasibility trials. Patient-based approaches for intervention planning may facilitate implementation and acceptability of interventions in practice.

Introduction

Asthma is a chronic inflammatory disease of the airways, affecting approximately 300 million people worldwide [1]. Despite the availability of effective medication, the burden of asthma for individuals and the society remains high [2, 3]. A key reason for this is the poor adherence

to ICS, with nonadherence rates ranging between 22-70% among people with asthma, which acts as a major barrier to optimal treatment outcomes [4-6].

Patients' beliefs about prescribed medication are important determinants of medication adherence, particularly how they judge their personal need for the treatment relative to their concerns about the potential adverse consequences of taking it [7]. Many patients with asthma doubt their personal need for daily ICS or have concerns about ICS, even when they experience no 'side-effects' [8-10].

Doubts about ICS necessity often arise from the patients' beliefs about asthma [10]. To be convinced of the need for a daily treatment we must see a close fit between our understanding of the problem (the illness) and the proposed solution (the treatment). Many patients with asthma simply do not see a good fit. The medical model of asthma as a chronic condition that requires daily preventative medication may be at odds with their experience of asthma as an episodic condition in which symptoms come and go [10, 11]. Daily ICS use may not make sense to them if their belief is 'no symptoms, no asthma" [12]. Many patients are concerned about the potential harm of corticosteroids. Concerns about corticosteroids as a medicine class are often linked to more general suspicions of pharmaceuticals and preferences for 'natural remedies' [11]. ICS concerns become more salient when the patient doubts the necessity of daily ICS [8].

Disconnects between patients' common-sense interpretations of their illness and treatment and the medical rationale for treatment, are a common reason for nonadherence across long-term conditions [7]. For this reason the National Institute for Health and Care Excellence (NICE) medicines adherence guideline recommends that consideration of patients' beliefs about treatment (necessity and concerns) should be a core component of interventions to support informed treatment choices and optimal adherence [13]. Many adherence interventions so far

have been ineffective [14, 15], mainly because they focus on educational, regimen altering or reminder strategies which are all of a practical nature [15], without considering important perceptual factors, such as medication beliefs [16]. To take account of the common beliefs described above, Horne has suggested that explanations of asthma and preventer treatment should be structured in a novel way that considers patients' illness perceptions and treatment beliefs. He proposes presenting the condition as the body 'out of balance' and the treatment as replicating natural processes for restoring balance [11, 17].

As nonadherence is often driven by a person's common-sense representation of their asthma and ICS, it is important to develop patient-centered interventions by understanding and accommodating the perspectives of the individuals who will use the intervention. Such a 'person-based' approach allows to supplement existing evidence and theory with new primary qualitative research with important stakeholders and can help define relevant components of an intervention in more detail [18, 19]. Incorporating patient perspectives early in the intervention development process can – directly or indirectly – help to confirm initial intervention ideas but also highlight where assumptions drawn from theory might have been misleading.

In this study we evaluated two different intervention approaches that both address medication beliefs in adults with asthma, using a person-based approach. By using this approach in the early stages of intervention development, we assessed patients' initial responses to and the initial acceptability of those alternative approaches, prior to running more costly feasibility trials.

Methods

We conducted three face-to-face focus groups between October 2016 and February 2017 in Central London to explore experiences of people with asthma and asthma medication and to collect feedback on two novel asthma interventions. Focus groups offer some unique advantages over individual interviews as the method facilitates in-depth discussion of shared experiences. This can lead to snowballing effects of information provided, often allowing for a wider bank of data to emerge as well as a greater spontaneity of participant answers [20]. The study was approved by the University College London Research Ethics Committee (REC ID 9293/001).

Sampling and recruitment

Participants were eligible if they were adults (≥18years), diagnosed with asthma, prescribed ICS, fluent in English, and able to attend the focus group in person. The study advertisement additionally stated that it was desirable for study participation if they were either currently experiencing problems with medication adherence or had experienced problems in the past.

Participants were recruited through advertisements on social media platforms Twitter and Facebook, including the Asthma UK and National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care (NIHR CLAHRC) North Thames respective social media sites. The advertisement was also distributed in the Asthma UK, NIHR CLAHRC North Thames and University College London email newsletters.

Interested participants contacted the researchers by email or phone. We allowed a maximum number of 10 participants per session. All participants were given an information sheet and a consent form to sign prior to the focus group. Participants completed an optional, brief demographic questionnaire about their age, ethnicity, education level, perceived asthma

severity and previous hospitalizations/Accident and Emergency attendances, but this was voluntary. All participants were given a monetary compensation of £30 plus travel costs.

Initially, we used a convenience sampling method, where all those participants meeting the inclusion criteria were invited. However, after the first two focus groups, we refined our recruitment strategy and used purposive sampling to increase the variation of participant ages and backgrounds (e.g. student, employed, retired).

Procedures

Focus group discussions were semi-structured using a topic guide, which was developed through discussion among the research team and based on the research around necessity and concerns medication beliefs [7, 10]. It was pilot tested in a group of students to ensure questions were clearly understood and allowed for open discussion. Two focus group interviews lasted two hours, while one lasted 1.5 hours due to delays in participant arrival.

The sessions were conducted in a seminar room within the researchers' office building. They commenced with a discussion about experiences with asthma and treatment, using open ended questions to explore spontaneously generated beliefs, to ascertain whether any new or contradictory issues with adherence were revealed. Participants were then asked to respond to two alternative intervention approaches addressing medication and illness beliefs, which differed in the language (medical vs non-medical), concepts and psychological techniques used. This paper will focus on the intervention development part of the focus group.

Intervention approaches offered to participants for discussion

Two intervention approaches (Approach 1 and Approach 2) were evaluated.

Approach 1: Reframing asthma and ICS with the concept of balance

Approach 1 was based on the theoretical knowledge around ICS necessity beliefs and concerns [11]. Based on Horne's proposed approach, a story was developed using reframing to offer a common-sense rationale for ICS by creating a fit between the representation of asthma as a chronic condition and necessity beliefs about ICS. This reframing approach presented Horne's novel asthma model using the concept of balance in the lungs. Instead of talking about inflammation, we explained asthma as an "over-reaction" of the lungs in the presence of triggers. To address ICS concerns, steroids were reframed as being "natural helpers" in our bodies, preventing organs from overreacting. Consequently, ICS should be seen as "topping up" those natural steroids and restoring balance in the lungs. The language used was non-medical, whilst still communicating a medically accurate message. An example statement was "In fact asthma is caused by your lungs being over-reactive, they go over the top! So you need the daily inhaled steroids to bring them back into balance and to ensure they stay in balance all the time".

Approach 2: The Vicious Cycle of ICS nonadherence

Approach 2 also focused on a common-sense fit of illness and necessity beliefs by using the concept of salience of health consequences of nonadherence. This was presented as a vicious cycle. We differentiated between asthma symptoms that can be felt by the patient (e.g. coughing) and those processes in the lungs (e.g. inflammation), which patients may not be aware of. Within the vicious cycle, asthma was depicted as inflammation in the lungs which does not cause acute symptoms immediately, leading to the feeling that ICS is not necessary. Inflammation increases unnoticed and when triggers cause the airways to narrow, this can lead to an asthma attack requiring a course of oral steroids to normalize the inflammation in the lungs. Daily use of ICS was presented as the solution to break free of this vicious cycle that would repeat itself without daily ICS treatment. The language used was more medical than in

Approach 1, e.g. “You’re feeling more wheezy and breathless, your asthma is affecting your daily life. Your airways are becoming very narrow and muscles around them tighten – any trigger or infection can cause an exacerbation!”.

Three researchers (CK, MM, RH) facilitated the first focus group, and the remaining two focus groups were facilitated by two members of the research team (CK, MM). The group discussions were audiotaped and transcribed.

Data analysis

Transcripts were analyzed independently by two researchers (CK, MM) using theory-based thematic analysis [21] and grouping feedback on the novel intervention ideas into thematic categories. Please see figure one for the coding tree used for data analysis. Demographic data was pooled using descriptive statistics.

Results

A total of 49 people expressed their interest in the study. Thirteen people were rejected for inclusion because the maximum number allowed per group had been reached, four people did not meet the eligibility criteria, eight declined to participate due to travel or date restrictions and five people did not attend the session at short notice. Nineteen participants (18-60 years old (M = 27, SD = 11)) attended the focus group interviews. When no new themes arose from the third group and feedback to proposed intervention content ideas remained consistent, recruitment was stopped. Table 1 outlines the participant characteristics. A total of 79% of participants completed the full voluntary demographics questionnaire.

Approach 1: Reframing asthma and ICS with the concept of balance

Linking common sense-illness beliefs and necessity for ICS

Reframing asthma as an overreaction of the lungs which is preventable by regular ICS-use, by keeping the lungs 'balanced', was welcomed by participants as a novel way to describe asthma. Participants found the use of a clear storyline to draw the logical connections between asthma mechanisms and the different kinds of inhalers helpful for understanding the necessity of ICS in the treatment of asthma. The traditional, medical terminology and the focus of the information participants previously received may have (unintentionally) supported the importance of the reliever rather than ICS.

"… hearing that explanation, it's really succinct, … it just reminds you of what's actually happening, keeps you well informed, and when you are well informed you are more likely to … do what you are supposed to do …" (Female, 20, student, group 1)

"I think most of the time when … someone's explained it to me, it's mostly been about taking the inhaler, the reliever inhaler, and how you manage an attack. Or kind of, the symptoms, the wheezing. … rather than, kind of actually how the steroids and all, fit into this picture." (Female, 24, working full-time, group 3)

Addressing ICS concerns

Participants perceived the reframing of steroids as natural helpers preventing over-reactions as helpful and reassuring. It lowered their concern of taking 'chemicals' into their bodies and framed it into an imagination of supporting natural processes in the body.

"I like the part that you added about our body producing natural steroids … So, the fact that you put that in there, sort of puts your mind at ease, to think, you know, I'm just having a top up of something." PT5 (Female, 24, working full-time, group 3)

Some participants felt that describing inhaled steroids as substances similar to those naturally occurring in the body might sound deceiving to some, especially because the artificial look of the inhaler counteracts the image of natural steroids. They felt like understanding the comparison might require people to have a basic understanding of the scientific background.

"… I quite like the way you kind of explained it but you said it's kind of a natural… I think because of the way the inhaler is, it looks quite scientific to me … an artificial thing … so by just being told oh it's a natural thing I don't quite know if I would buy into that almost … if didn't know the science behind it … ." (Male, 20, student, group 2)

Impact on the perception of self

The novel explanation of asthma was perceived as a change in perspective, which potentially counteracts a perceived stigma of weakness. Compared to the more traditional asthma representation, this explanation was seen as a more positive approach, by implying a healthy mechanism that is triggered too easily in people with asthma rather than suggesting a deficiency.

"I like it, because you are like reshaping essentially the way, … diseases are looked at, … people see that as something that is outside the norm, whereas you are like redefining the norm … like a paradigm shift" (Female, 20, student, group 1)

"… it sort of implies that you're not like deficient in something. It's like you still have the same mechanism but you just do it too much …" (Female, 24, student, group 2)

Perceiving the reframing of asthma and steroids as providing a more positive perspective into their condition might help people with asthma accepting their diagnosis. They felt this might increase their motivation to take ICS daily.

'… Maybe a more positive approach puts these defenses down so you can more openly face the reality' (Male, 23, student, group 2)

"… I think is a bit more of a motivator, … we would be more motivated to use our preventer because of the story." (Male, 20, student, group 1)

Approach 1 was further perceived as putting less blame on the individual for not being fully adherent, which was in contrast to what participants had previously experienced in clinical consultations.

'It doesn't guilt trip … I've been guilt tripped by doctors about it. It's just like what did you do? You must be doing something wrong. … I already feel bad enough that I had to go. Don't make me feel worse.' (female, 30, working full-time, group 2)

Critique of the approach

Some participants felt that they already knew too much about asthma for one 'reframing story' to change their perceptions. Still, they acknowledged the general positivity of the approach and thought that it might be more valuable for younger patients and/or to change a potential perceived stigma of weakness and misrepresentation of asthma in the society.

"… I already have like the background in my mind … if I had known the story when I was younger, definitely I think it would have changed, but I think for now… it's difficult to make your change your mind … but for children, if you feel like it's not a weakness but rather just, just a different way of being, I think that would make a difference. " (Female, 21, student, group 1)

"I think with the balance model, you could use for people without asthma and with asthma, like you can show it to everybody and it will create that good imagery." (Male, 20, student, group 1)

Perceptions of language used

Participants found the language used to be non-medical while perceiving the explanation to be medically accurate, which was appreciated by the majority. Reframing information about asthma and steroids was well received as participants felt the language was less threatening and easier to understand than more traditional explanations they had heard previously. They felt that making information more interesting and easy to understand is often mistaken as being inappropriate for adults, but most participants appreciated the effort of presenting information in a more engaging way.

"Probably the explanation is more simple … to understand." (Male, 60, retired, group 3)

"I like the way you kind of explained it … it's just your lungs overreacting as opposed to … it's the little sacs inside your lungs which go into a spasm, which then constrain … because people switch off." (Female, 30, working full-time, group 2)

"… adults still need a nice colorful story and if you don't have talking animals in it, you can still make it interesting." (Female, 30, working full-time, group 2)

Approach 2: The vicious cycle of ICS nonadherence

Linking common sense-illness beliefs and necessity for ICS

Patients' initial reactions when presented with the vicious cycle conceptualization of preventer nonadherence were negative. They felt that this representation of asthma and the preventer was already familiar to them and for many participants it didn't apply to their experience with asthma. They found that while they may experience intermittent worsening of their asthma symptoms, they don't usually go through the full cycle of having an asthma attack.

"I'm not a huge fan mainly because I already know all this … and it also kind of goes to the really extreme." (Male, 24, student, group 2)

"… it's the same cycle we sort of know about, … I haven't thankfully been the full circle for several years now." (Male, 30, working full-time, group 1)

However, a few people thought the representation of the vicious cycle provided them with details and a clear understanding of asthma mechanisms and consequences which might potentially give them a rationale to take the preventer inhaler more consistently.

"… it's more detailed, it gives me a better understanding, it gives me background information, so I am more likely to understand the reasoning behind it and then therefore stick to it" (Female, 20, student, group 1)

Critique of the approach

The concept of a vicious cycle was seen as a technique of fear mongering among participants, which was perceived by some as negative and threatening and by others as emphasizing the seriousness of asthma hence providing a rationale to take the preventer. Still other participants thought a 'cycle' suggests that it might be difficult to ever break free of it, which was perceived as being demoralizing.

"… This is serious. Like I should probably take my inhaler. So I think in a way the scare mongering does force you to take your inhaler." (Female, 24, student, group 2)

"… a cycle, so doesn't that suggest that you will never get out' (Male, 30, working full-time, group 1)

Impact on the perception of self and perception of language used

The language used was viewed as being 'scientific' or 'medical' by most participants, which some thought emphasized the negative image of having a chronic condition, such as the association with weakness.

"Yes, that could be just the use of the words like steroids and antibiotics and wheezy and A&E, and you think oh man, I am falling apart again." (Female, 21, student, group 1)

Other

Independently of the intervention approach, visual aids such as pictures of inhalers and mechanisms were desired by participants, especially for those people having language barriers or for those with reading impairments.

"… I think if you put like images in each side, like a sort of small image that explains what happens, … I live with two immigrants and they don't speak that well English, but they have asthma also ...." (Female, 21, student, group 1)

"I quite like the pictures. I'm dyslexic as well and I automatically go for pictures rather than words." (Female, 22, student, group 2)

Discussion and Conclusion

This study explored how adults with asthma viewed two alternative novel intervention approaches using a person-based approach to intervention development. This allowed insights into peoples' experiences with asthma and ICS, and their thoughts about the two alternative intervention approaches. In this study we introduced a new way of communicating asthma that is based on psychological theory, and described a method to evaluate and refine novel intervention content to maximize its acceptability prior to running a costly feasibility trial.

Discussion

Focus group feedback generally confirmed the acceptability of a novel explanation approach which aims to reframe asthma and steroids by using the concept of balance in the lungs based on research by Horne and colleagues [11, 17]. Reframing asthma using the concept of balance and over-reactive lungs rather than a more medical description of inflammation and airway muscle contraction was received positively by most participants; it was perceived to be a novel approach with the potential to change their perceptions of asthma. Initial acceptability suggests that this may be a successful strategy to provide patients with a common-sense story to view their asthma as a chronic rather than episodic condition, independent of the presence of

symptoms. This can consequently increase necessity beliefs about ICS [11, 12]. Similarly, feedback suggested that reframing steroids as naturally occurring 'helpers' preventing over-reactions in our bodies may reduce ICS concerns. These findings underline the potential of the theory-based reframing approach to change medication beliefs, which have been previously linked to adherence [7]. This may be especially effective in people newly diagnosed with asthma. They potentially haven't formed a detailed illness representation with the corresponding ICS beliefs at the point of diagnosis, and therefore providing them with a coherent explanation linking illness and medication beliefs may be crucial for their future adherence [22]. Findings further suggest that using a concept of balance to explain asthma and ICS may have a positive impact on the sense of self, by presenting asthma without implying a negative image of weakness and labelling people with asthma as being deficient. Sense of self has previously been linked to medication beliefs and adherence, as well as general acceptance of an asthma diagnosis [17, 23].

The vicious cycle of nonadherence focused on communicating health consequences of nonadherence to ICS, with the aim of increasing necessity beliefs. However, this approach did not reach a high level of acceptability. This explanation was perceived as triggering an emotional response of fear and therefore conveying a negative feeling towards asthma. While few participants felt that emphasizing the severity of asthma might increase their necessity beliefs about ICS, perceiving high levels of fear may generally result in denial and inaction [24]. Additionally, the vicious cycle representation was not perceived as being novel and succinct from information participants had previously received, and participants often felt that not all aspects of this approach applied to them. Previous research shows that perceived personal relevance can impact the emotional and cognitive response to threatening information. Hence, many people might choose to ignore the potential health consequences, because of a low personal relevance [25].

Overall, participants appreciated the lack of medical jargon in the reframing approach of asthma (approach 1), perceiving it as easier to understand and more positive. This is in line with findings suggesting that everyday language leads to better understanding in patients compared to medical jargon [26, 27]. Better understanding of asthma may be important to avoid misconceptions about the illness and medication [12]. Further, feedback suggested that information should be supplemented by appropriate imagery for reasons of simplicity and to aid understanding without language barriers. Adding pictures to health communication may improve recall of information, but also behaviors such as adherence [28]. Exploring this channel further may therefore be relevant for future research.

The present study provides valuable patient feedback for future interventions, but due to the nature of qualitative research designs, findings are not readily generalizable. The large proportion of students in the sample may over-represent the point of view of younger adults. However, recent figures from the British Lung Foundation show that young adults are the group most likely to have been diagnosed with asthma at some point in their lifetime [29]. Additionally, a younger patient age has been associated with nonadherence in a number of studies; in particular patients between 14–25 years have been found to report using preventer inhalers less than older patients [30]. This makes them an important group to research and target for improving adherence. As recruitment was conducted via a charity where participants volunteered to participate, the participants may be more engaged with their asthma and asthma medication compared to the general asthma population.

Nevertheless, the positive reception of a simplified reframing approach to asthma in our sample is encouraging, as participants perceived this new explanation of asthma based on the concept of ‘balance in the body’ as novel, positive and providing a new perspective, despite potentially having vast pre-existing asthma knowledge. Based on these positive focus group findings, the

idea of reframing asthma and steroids using the concept of balance has been refined and is currently being evaluated for its effectiveness and acceptability in a bigger asthma sample.

Conclusion

The reframing approach to asthma using the concept of balance and over-reactive lungs showed a higher overall acceptability than the vicious cycle of ICS nonadherence. This study suggests that the reframing approach to asthma may have the potential to communicate a common-sense rationale for ICS adherence by linking illness and medication beliefs. The study further highlights the importance of using a person-based approach in the intervention development process. This intervention approach is currently under investigation in a National Institute for Health Research, Collaboration for Leadership in Applied Health Research and Care funded feasibility trial.

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Tables and figures with captions

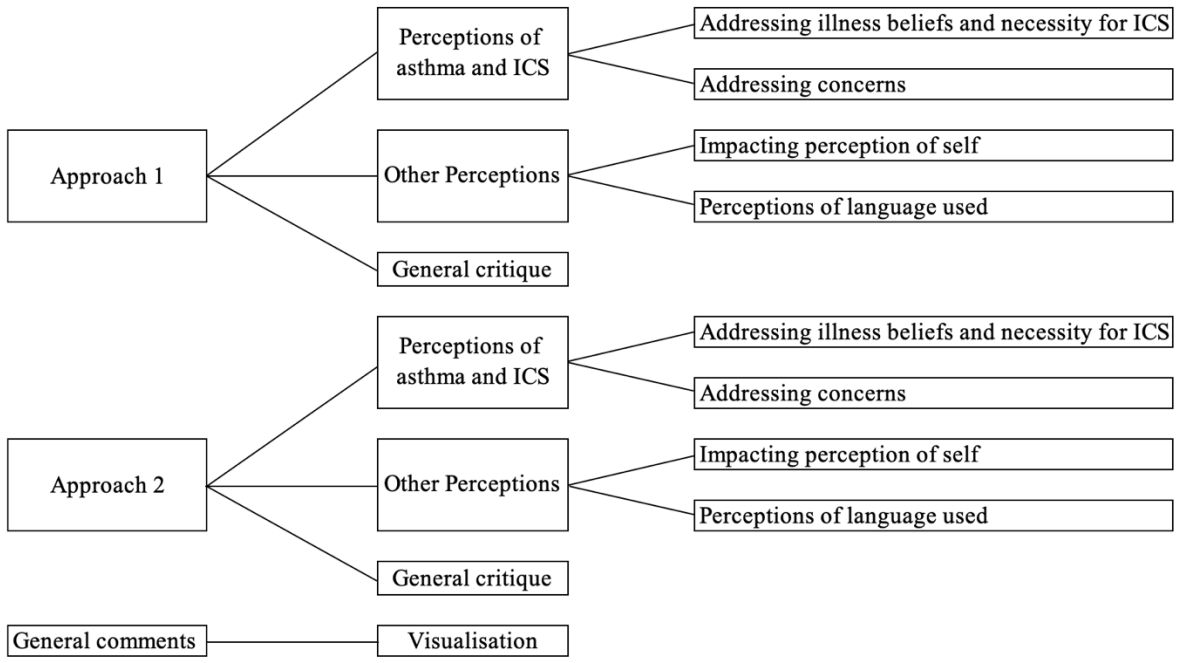

Figure 1. Data analysis coding tree.

Table 1.

Demographic characteristics of the sample, reported for each focus group.

		Group 1 (n = 6)	Group 2 (n = 8)	Group 3 (n = 5)	**All participants (N = 19)**
Age [M (SD)]		21.7 (4.2)	24.1 (3.5)	37.6 (16.0)	26.9 (10.6)
Sex [n (%)]	Male	2 (33)	5 (63)	1 (20)	8 (42)
	Female	4 (67)	3 (38)	4 (80)	11 (58)
Ethnicity [n (%)]	Asian/Asian British	1 (17)	1 (13)		2 (11)
	Black/Black British	1 (17)	1 (13)		2 (11)
	White British	2 (33)	4 (50)	2 (40)	8 (42)
	White Other	2 (33)	1 (13)	1 (20)	4 (21)
	Mixed		1 (13)	2 (40)	3 (16)
Asthma severity [n (%)] (N = 15)*	Mild		4 (50)	2 (40)	6 (46)
	Moderate	1 (17)	3 (38)	1 (20)	4 (21)
	Severe	1 (17)	1 (13)	2 (40)	3 (23)
Past hospitalisations [n (%)] (N = 16)*	Yes	3 (50)	5 (63)	3 (60)	8 (62)
	No		3 (38)	2 (40)	5 (39)

*Note: As the demographics questionnaire was voluntary for participants, data was not available from all group 1 participants for all items.