



Recruiting ethnic minority participants to a clinical trial: a qualitative study

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Complete List of Authors:	MacNeill, Virginia; Queen Mary University London, Primary Care and Public Health Nwokoro, Chinedu; Barts and The London School of Medicine and Dentistry, Griffiths, Chris; Barts and The London School of Medicine and Dentistry, Grigg, Jonathan; Barts and The London School of Medicine and Dentistry, Seale, Clive; Queen Mary University London, Primary Care and Public Health
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Recruiting ethnic minority participants to a clinical trial: a qualitative studyVirginia MacNeill¹, Chinedu Nwokoro¹, Chris Griffiths², Jonathan Grigg¹, Clive Seale²

¹Centre for Paediatrics, Blizard Institute, Barts and the London School of Medicine and Dentistry, Queen Mary, University of London, 4 Newark Street, London E1 2AT, UK

²Centre for Primary Care and Public Health, Blizard Institute, Barts and the London School of Medicine and Dentistry, Queen Mary, University of London, 58 Turner Street, London E1 2AB, UK

Correspondence to:

Dr Chinedu Nwokoro MBBChir MD

Centre for Paediatrics

Blizard Institute

4 Newark Street

London E1 2AT

Email: c.nwokoro@qmul.ac.uk

Telephone: 020 7882 2280

Fax: 020 7882 2195

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VM is a Qualitative Health Research Fellow

CN is a Respiratory Paediatrician and Clinical Research Fellow

CG is a General Practitioner and Professor of Primary Care

JG is a Paediatrician and Professor of Paediatric Respiratory Medicine

CS is a Professor of Medical Sociology

Contributorship

VM carried out the interviews, analysed data and wrote the initial draft of the paper. JG led the original research bid; CG and CS were co-applicants. CS supervised VM's data collection and analysis. JG, CG and CN contributed to the drafting of the paper. CS is guarantor.

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There are no competing interests.

Data Sharing Statement

Consent for publication of raw data obtained from study participants. Original transcripts are available from the corresponding author on request.

Licence Statement

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Abstract**Objectives:**

To compare the motives and experiences of different ethnic groups participating in a randomised double blind placebo-controlled trial of montelukast in preschool wheeze, and to assess parents' or guardians' understanding of trial procedures and their implications, including the collection of genetic material.

Design:

Qualitative interviews with parents or guardians.

Setting:

Interviews occurred in the homes of London children recruited to a national multicentre clinical trial following primary and secondary care attendance with wheeze.

Participants:

42 parents (20 of Bangladeshi origin, 10 white UK, 12 other ethnicities) of preschool children enrolled in a clinical trial.

Results:

Bangladeshi families were relatively reluctant to participate in the qualitative study, despite strong engagement with the parent study.

Anxiety related to wheezing was a common primary motive for trial enrolment. Parents viewed the trial as a route to improved treatment. Verbal delivery of trial information was more effective than study literature, especially for Bangladeshi families, with low parental literacy and high levels of trust in medical professionals contributing to this effect. All ethnic groups expressed a low understanding and/or retention of essential study concepts such as randomisation and genetic testing.

Conclusions:

Bangladeshi families are particularly motivated to participate in clinical trials despite variable comprehension of study concepts. This motivation is more strongly contingent on strong researcher-subject rapport than on the quality of study literature. Trial teams seeking to recruit from South Asian populations should emphasise face-to-face verbal explanation of trial concepts and procedures and consider modified trial literature.

Article Summary

Article Focus:

- South Asians and ethnic minorities are underrepresented in clinical trials, affecting applicability of results.
- South Asian group representatives suggest that a personal approach by researchers may improve recruitment.
- Parents enrolling young children in trials often have poor understanding of the implications of consent, whether this varies across ethnic groups is unknown.

Key Messages:

- Self-interest as well as altruism influence parental decision to enrol in a paediatric respiratory clinical trial.
- Decision to enrol is influenced more by trust in the research team than by written information.
- Careful verbal explanations of trial procedures, advantages and disadvantages are particularly important for parents of Bangladeshi origin.

Strengths and Limitations:

- Data from a study population historically difficult to engage in quantitative or qualitative clinical research.
- The sample size is small but adequate to achieve data saturation.
- There is an absence of data on parents declining to participate in the parent study.

Introduction

The under-representation of South Asians and other ethnic minority groups in clinical trials affects the generalisability of study findings and ultimately contributes to inequities in access to health care.(1, 2) Marked ethnic disparities exist in asthma outcomes(3) and ethnically delineated barriers to participation in trials concerning asthma interventions have been identified. These include a residual stigma attached to the asthmatic label, anxieties related to understanding the implications of participation, worries about the effects of trial medications, as well as cost and time concerns.(4) Suggested solutions include: provision of incentives, use of multilingual trial literature, employment of personal approaches and addressing researchers' reluctance to invite participation from the full cultural and linguistic spectrum.(4-6)

Currently there is poor understanding of the perspective of ethnic minority parents involved in paediatric clinical trials. Previous work has explored the role of parents as responsible decision makers co-reliant on the researchers and research governance procedures for guidance and protection.(7) Significant elements include parents' poor comprehension of the trial process,(8) the parental emotional turmoil-related to paediatric illness, and confusion born of the blurring of ethical boundaries between clinical and research practice.(9-11)

The current study is embedded within a randomised controlled trial (the parent study) of the genetic determinants of the efficacy of intermittent montelukast in preschool wheeze and provides an opportunity to investigate the perspectives of the parents of trial participants. Preschool wheeze (PSW) is a common but poorly understood disease of early childhood equally prevalent in UK children of South Asian and European origin.(12) The ethnically diverse setting of the recruiting institution permits the principal aim of this study which is to compare attitudes and experiences of participating families across ethnic groups, including a significant number of participants of South Asian (Bangladeshi) origin.

A secondary aim arises from the fact that both positive and negative public perceptions of pharmacogenetics exist.(13) A recent focus group study involving diverse ethnic minority participants in biobank research found generally positive attitudes, with participation driven by perceptions of personal or collective benefit, despite limited understanding of genetics.(14, 15) Hence this work aims to describe ethnic variation in participants' understanding of the genetic element of the trial.

Methods

Parent study procedures

Families received a trial information pack and subsequently discussed the study with the research team. Written and real-time verbal Bengali translation was available as required. Amenable parents then gave written consent after which a mouth swab (for leukotriene-pathway genes) and urine sample (for leukotriene levels) were collected. Parents agreed to administer a ten day course of medication (randomly allocated to montelukast or placebo) at the onset of a cold or wheezing symptoms, and to complete a daily diary record for the same period. They also received progress calls from the clinical research team at regular intervals and were encouraged to phone if they had any queries or concerns. Children were followed up for one year and the need for unscheduled respiratory medical attendance assessed. The qualitative study (QS) was based at the East London host centre of this multicentre trial and involved an audio-recorded semi-structured interview with parents of enrolled children.

Participant recruitment

All participants in the trial and the qualitative sub study received written information about the study. 139 parents gave formal written consent for their child to be enrolled in the trial and 85 of these parents gave written consent to a qualitative interview at the same time (Table 1). The initial plan was to sample purposefully from the 85 consenting parents, aiming for maximum variation (16) in terms of ethnicity, gender and other variables and then theoretically, according to iterative analysis of initial interviews.

Data generation

Individual interviews were considered the most appropriate method for data collection as this ensured confidentiality. A semi-structured interview guide (Box 1) for the interviews was developed following a literature review and discussions between VM and CS. Interviews were conducted by VM, an experienced non-clinical qualitative researcher with an interest in the development of healthcare services in partnership with the patient population. Each interview took place in the parent's home and lasted 25-60 minutes. Preschool children were present in many instances. Interviews were conducted in English except one interview which required the assistance of a Bengali interpreter.

Box 1: Topics included in the semi –structured interview guide

1. Family and child background information
 - Child’s history of wheeze
 - Treatment and diagnosis
 - Impact on child/parents/family
2. Parents experiences of joining the trial
 - Motivations
 - Consent and research governance processes
 - Attitudes towards the collection of DNA and genetically guided therapy
3. Parents attitudes to and experiences of giving the trial drug to their child.

Data analysis

Interviews were audio-recorded and professionally transcribed verbatim. CS also reviewed a sample of interview transcripts during the course of the data collection period. Transcripts and field notes were imported into NVivo9, a qualitative data analysis programme (18). VM and CS developed a coding framework that drew on the research questions, previous research about patient experiences of taking part in clinical trials and themes that emerged in the course of the analysis. The data were systematically coded and analysed, using a modified grounded theory approach (19) that incorporating the constant comparison technique to elicit key themes and explore deviant cases (20, 21)

Ethics

The study was reviewed and granted approval by the South East Research Ethics Committee (09/H1102/110). Written informed consent for QS was included as part of the CT consent process and reconfirmed immediately before the qualitative interviews took place.

The QS adhered to the RAT qualitative research review guidelines (22)

Results

Of the 85 parents who gave written consent to structured interview at parent study enrolment only 42 subsequently participated in a face to face interview. The reasons for non-participation are as stated in Box 2. The remaining 42 parents agreed to a face to face interview, which took place over a seven month period. There is no ideal sample size for qualitative studies (17) and this was a sufficient number of interviews within this opportunist sample to achieve data saturation.

Box 2: Reasons given for decline or no response to request for qualitative interview	Number of parents
No response	14
Declined – no reason given	11
Declined – no time (employment-related)	4
Declined – unable to speak English	5
Declined – no time (heavily pregnant or caring for newborn)	4
Declined – annual or religious or imminent extended holiday	5
Total number of parents	43

At QS commencement 139 families had consented to study enrolment; Bangladeshi participants were relatively overrepresented in the parent study and white British underrepresented. Bangladeshi parents taking part in the parent study were less likely than parents of ‘other’ ethnicity to be interviewed for the study reported here. Table 1 shows ethnically delineated differences in study participation.

Table 1: Patterns of participation by ethnic group (23)

	Bangladeshi	White British	Other**	Total
Percentage of Local <15 Population by ethnic group*	22,200 (50%)	14,500 (33%)	7,500 (17%)	44,200 (100%)
Parents with children enrolled in Parent Study at time of QS	94 (68%)	24 (17%)	21 (15%)	139 (100%)
Parents consenting to QS at time of enrolment to Parent Study (% of parents enrolled, 95% CI)	48 (51%, 41-61)	17 (71%, 51-85)	20 (95%, 76-100)	85
Qualitative interview completed (% of parents enrolled, 95% CI)	20 (21%, 14-31)	10 (42%, 24-61)	12 (57%, 37-76)	42

*There is no information available regarding ethnicity of the local under 5 population. Data regarding under-15 children is deemed an appropriate surrogate given that the overwhelming majority of local pre-schoolers survive to their teens and there is no evidence of an ethnically divergent change in local birth rates in recent years.

**Other interviewed parents: Africa (6), Caribbean (2), South America (1), Middle East (1), China (1)

We proceed to outline the characteristics of participants, then report on the themes that emerged from the interviews.

These include:

1. Reasons parents gave for enrolling their child in the trial,
2. Participating parents' experience of the consent process and understanding of written and verbal information provided at the outset of the trial, in particular their understanding of the randomisation process,
3. Participating parents' understanding and response to the collection of genetic information.
4. The nature of participating parents' consultations with other people before deciding to take part.

Throughout, we report on differences and similarities between Bangladeshi and other participants.

Characteristics of participants

Table 2: Characteristics of qualitative interview participants

		Bangladeshi	White UK	Other
Demographics				
Male		6	2	2
Female		14	8	10
Age in years (mean (SD))		35 (7.8)	34 (6.2)	36 (4.3)
Language				
1st Language	Bengali/Sylheti	19		
	English	1	10	4
	French			2
	Arabic			2
	Mandarin			1
	Creole			1
	Portuguese			2
Fluency in spoken English*	Excellent	5	10	4
	Good	1	0	0
	Fair	5	0	5
	Poor	9	0	3
Socioeconomic				
Educational attainment	Left before 16 years	1		
	GCSE or equivalent	8	6	3
	A level or equivalent	1	0	3

	Graduate degree	1	4	3
	Postgraduate degree	1		2
	Not answered	8		1
Occupation of highest earner in family	Higher managerial, administrative & professional	1	2	2
	Intermediate	3	1	3
	Routine and manual	8	2	3
	Student			1
	Not answered	8	5	3
	Total	20	10	12

* Interviewer's judgement

The majority of respondents were female. Bangladeshi participants had poorer spoken English than other groups and were less inclined to disclose their level of schooling, perhaps indicating sensitivity regarding poor educational attainment. Most households reported at least one working parent, but the numbers engaged in full time, part time, or shift work were unclear due to guarded responses.

Parents of children in all groups reported anxiety related to their helplessness during wheezing attacks, often driven by the first hospital presentation. Major fears were of the potential for death or major long term disability. These concerns drove a preoccupation with monitoring their child's health, together with anxiety about the potential progression of a cold to a wheeze with the attendant hospital visit, investigations and treatment. These fears were important drivers for trial participation, with hopes that participation might contribute to improved treatment for wheeze. Box 3 shows interview extracts relevant to this theme.

Box 3: Anxieties about wheeze in children

When I am putting him in the shower he was difficult to breath, he goes (makes gasping sound) with his hand in his mouth and I was scared and then I had to call an ambulance...he stayed in hospital for two days.(24F-Brazilian)

He wasn't too good they said we have to keep him in and he had oxygen up his nose. It was horrible. So he was in hospital for three days. That was the worst three days of my life. (41F-UK)

I'm so worried. My God. I know asthma may kill so I'm very worried (01F-Bangladeshi)

'My worst fear was that if I'm not with him or something like that....not breathe or...I don't know, I don't know much about asthma. I don't want him to get that. (08F-Egyptian)

'I can remember saying to (husband) very clearly if he dies don't come and collect me because I don't want to leave without him' (19F-Caribbean)

'I really didn't know how bad it was and how it can affect a child. And I really didn't know it was going to be the start of this long process of hospital after hospital after hospital.' (09F-UK)

'I am looking for a final treatment for her because this disease is not good for her health you know so I am looking for much better treatment for her and to find a treatment which is better for her whole life.' (33FM-Bangladeshi).

1 This was the emotional context within which parents were approached by the clinical trial team and asked if they would
2 consider enrolling their child into the parent study. Parents reported being approached while inpatients or during follow-
3 up appointments in primary or secondary care. Most children were already on prescribed medication for wheeze.
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8 Half of the parents (11/20 Bangladeshi, 6/10 UK, 4/12 other) said that their primary reason for enrolling their child was
9 that they hoped it would benefit their child in curtailing or curing the wheeze. A subset of these believed that the trial
10 medicine represented an individual treatment regime for their child, perhaps conflating research with personal treatment.
11
12 Others also viewed it as a route to additional information, treatments and medical attention by skilled physicians (Box 4).
13
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16
17 A third (15/42, of which 5/20 Bangladeshi, 4/10 UK, 6/12 other) said that their aim was to help other children by
18 contributing to the advancement of medical knowledge (although benefit to others was secondary to a consideration of
19 potential benefit to their own child). Only four parents (2/10 UK, 2/12 other) voiced a wholly altruistic outlook by
20 pointing out that the results of the trial would be unlikely to benefit their own child.
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27 A few parents (2/20 Bangladeshi, 1/10 UK, 0/12 other) based their decision to participate in the trial primarily on their
28 trust in the research team, these families appeared not to differentiate between trial researcher and healthcare provider
29 roles. Parents felt reassured that they could opt out of the trial at any time and, particularly if their child experienced side
30 effects.
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Box 4: Other reasons for taking part*Benefit to child*

I wanted to see if it helps my daughter, to see if it got rid of her wheeze. (42F-Bangladeshi)

They said if you do this study your daughter is going to get better. (25F-Bangladeshi)

It's an extra medicine for my daughter that will help her, and it helps her stay at home rather than going to the GP or hospital all the time. (42F-Bangladeshi)

A very good way of you know, getting him seen by good doctors ... and hopefully getting answers you're looking for' (05F-UK)

Benefit to others

[My child] won't really benefit but from it ...this is obviously a trial so that they can try and prescribe this medicine in the future for children. (29F-UK)

It's good for the future. All children. Not for her [child] because she has already got it now, but yes, all children of the world. (40F-African)

Hopefully it's good for other children and good for her. (6M-Chinese)

Trust in clinicians

I thought like, you know, it's from hospital, obvious it's good for him. So the doctor knows better than us. (02F-Bangladeshi)

Being in control

It's reassuring that they kept saying that at any time we can pull out. (21F-Bangladeshi)

They explained to me that the main side effect was sleep like sleep disturbance erm... and obviously if it was too much then just stop. (04F-UK)

Beliefs about the acceptability to their child and the effects of the substance they were given – whether montelukast or placebo - were clearly important motives in maintaining or discouraging continuing participation (Box 5). 4/20 Bangladeshi parents (but no others) believed there would be no side effects, reporting that this was what the trial researcher had told them. Even parents with a well-informed understanding of the trial process said they would consider withdrawing their child if they believed the medication was not having a beneficial effect. Three (one from each ethnic group) had already decided to discontinue, because their child did not like the medication or because it did not appear to

1 be effective, or because of perceived adverse effects. Three more (2/10 UK, 1/12 other) said they would consider
 2 dropping out for similar reasons if they believed that their child had been allocated the placebo drug, or if the medication
 3 seemed ineffective or harmful, indicating that subject recruitment and retention is driven strongly by the perceived
 4 likelihood of personal benefit.
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 9 **Box 5: Effects and acceptability of medication**

10 They just told me there's not going to be there, there is no side effects at all. (23M-Bangladeshi)

11
 12 Yes medicine he doesn't like. (22F- Bangladeshi)

13
 14
 15 I don't want there to be any side effects. Yes everything has got side effects but, it's the sleeping part and the
 16 behaviour that was another thing. I didn't want that to change. (41F-UK)

17
 18
 19 I think our first step would be if I thought he wasn't on the medicine, getting the medicine prescribed somewhere
 20 else. (05F-UK)

21
 22
 23 I mean the only reason I would come out of the trial was if I thought there was any erm... negative side effects. And
 24 we're now on our second dose of medicine and he's been totally fine. (10F-UK)

25
 26
 27 I'd go back to the hospital...and tell them the medicine you give to me maybe don't do anything. (07F-African)

28
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 30 The wheezing is still there and it was not going away, so I just said, I just stopped giving to him, I said I didn't
 31 think it was helping him at all. (32F-Caribbean)

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 37 *Information and consent*

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 39 **Table 3: Information and Consent**

	Bangladeshi	White UK	Other*	Total
Satisfied with initial information	20	10	12	42/42
Personally Read PIL	11/20	6/10	4/12	21/42
Had PIL read to them	5/20	4/10	6/12	15/42
Understanding of randomisation	5/20	7/10	3/12	14/42
Awareness that DNA sample taken	6/20	9/10	9/12	24/42

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 54 All parents reported satisfaction with the initial trial information they had received and that all queries were answered
 55 adequately. Retention was poor however, and by the time of the interview few could recall significant detail. The
 56 decision to consent was strongly influenced by the meeting with the clinical team.
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2
3 The patient information leaflet (PIL) was translated from English into Bengali but not into other languages. Interviewees
4 were often evasive regarding their reading of the PIL, suggesting that this was an area of sensitivity for some
5 respondents. Just 7 (41%) of 17 Bangladeshi respondents who gave direct answers claimed to have read the leaflet
6 (compared with 15/16 (93%) of non-Bangladeshis); a further 7 said they had not and three said that other family
7 members had read it for them. Box 6 shows comments made about the PIL. The length and detail of the PIL appeared to
8 discourage reading in some (mainly Bangladeshi) respondents, placing the emphasis more firmly on personal interaction
9 with researchers for communication of trial information.
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16 **Box 6: Comments about the patient information leaflet**

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19 Lots of pages. Yeah, little bit I read...He explained me nicely that time. I understand what he's saying but I can't
20 tell you now. I can't remember all of it. (01F- Bangladeshi)

21
22
23 Some of the first page and second page we did and then we was happy with this. We read we are so happy some of
24 the paragraphs is very nice but it carried on and on. (15M- Bangladeshi)

25
26
27 That time I was very busy and I don't have time to read it, and when I had time I forgot. (25F- Bangladeshi)

28
29
30 I understood what she explained so I didn't really bother to read that much. (38F-Bangladeshi)

31
32
33 Yes of course, I read everything. Erm, I did read it, I could have read more, erm but I am one of the people who
34 reads everything. I am used to reading complicated stuff in my work anyway. (30M-UK)

35
36
37 They were good explanatory, there was a lot of them but it's not the same as talking to somebody saying well look
38 I'm worried about and then they'll they put me right. I had a better understanding and you can't ask a question on a
39 bit of paper. (09F-UK)

40
41
42 It told me everything I need to know to be able to start the trial. (27F-Black UK)

43
44
45 Er....can't remember. Something. I have to think... because it was a long time ago. (08F-Egyptian)

46
47
48 I read it, well both myself and my partner read it and we did find it like yeah it was absolutely fine for us. (19F
49 Caribbean)

50
51
52 I read it....Just first the introduction, the introduction this research. (06M-Chinese)
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Understanding the research process

Just over a third of parents understood the principle of randomisation to some degree (5/20 Bangladeshi, 7/10 White UK, 3/12 Others). (see Box 7) Bangladeshi families were least aware that a DNA sample had been taken from their child (6/20 Bangladeshi were aware, 9/10 UK, 9/12 Others). Despite poor comprehension of personalised medicine and genetic testing concepts most respondents viewed the genetic component of the study positively.

Box 7: Understanding and acceptance of randomisation and DNA component*Randomisation*

I totally don't know if the powder is the ..er..blank one (06M-Chinese)

Well they said they were going to test so many people with this and so many people with that and then get the results and see what. 17F-Bangladeshi)

We are in a trial and we could be given a placebo or cure and that's done on a group of kids. (26M-Middle Eastern)

Yes, so I could have a treatment that is sherbet in other words. (27F-Black UK)

DNA component

They did tell me [its purpose] at the time but I really can't remember. (21F- Bangladeshi)

They told me, eh, I can't remember, sorry. (39F-African)

It's only if it didn't hurt him, it was only a swab from his mouth so no, that was fine. (04F-UK)

As long as it's not invasive (08F-Egyptian)

I'm sure it's only used for the medical and not generally. I think the only time it would be concerning is like I said if they were going to share the information. (21F- Bangladeshi)

I haven't really thought about it. It's just part of the one part of the study that needs to be that they're looking at. I don't think there's anything sinister being done. Everyone's going to end up on a DNA database somewhere. (05F-UK)

Consulting others

There were some differences between ethnic groups in how decisions were made to enrol their child in the trial. Some decided to consent as soon as they were approached but others sought advice from other people. Some (4/20) Bangladeshi respondents reported that they relied entirely on the medical profession to guide them but they were the only

1 group to express this. Some non-Bangladeshi respondents were able to call on medically qualified family members for
2 their advice or made use of the internet and other sources of pharmaceutical information. Very few respondents (3/42),
3 all of White UK ethnicity, reported receiving negative views about the trial from family or friends. Box 8 shows relevant
4 extracts.
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9 **Box 8: Other sources of information and reassurance**

10
11 It's from hospital obvious it's good for him. He...the doctor knows better than us. (02F- Bangladeshi)

12
13 I told him [my husband] and he said OK if you want to go you can go. (25F- Bangladeshi)

14
15 I looked at the internet I think.....where I work we've got an old copy of the BNF so I looked at that. (18M-UK)

16
17 I was pretty certain I think.. but his dad was a bit more reluctant because he's sort of thought it was a trial
18 medicine.... and then when I explained that montelukast was already a drug... and if he has asthma and it gets
19 progressively worse, there's a good chance it will be prescribed anyway, so.., (10F-UK)
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27 **Discussion**

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31 *Summary of the main findings*

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33 A major reason for parents agreeing to enrol their child in the trial related to their previous experiences of witnessing
34 their child having severe wheeze attacks. This caused anxiety in many parents, regardless of ethnicity, motivating them to
35 find an effective treatment. However some parents found it difficult to distinguish between clinical treatment and
36 research despite receiving information about the trial processes, including randomisation and the use of a placebo.
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41 A second reason for enrolment was the reassurance parents received that they would retain control, not only regarding
42 remaining in the study, but also regarding whether and when they gave their child the study medicine.
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47 Thirdly, most parents had confidence in the research team and preferred face to face meetings with the clinical trial
48 researchers to reliance on written patient information leaflets (PILs). They could ask questions directly of the research
49 team and found the prescribed and formalised information sheets too long. While none said that they had received too
50 much information about the trial, few had read beyond the first few pages. Bangladeshi parents were particularly
51 disadvantaged by the fact that, although the information sheets were translated into their language, some were unable to
52 read at all.
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3 The study found a lack of curiosity about research processes and practices amongst all ethnic groups. Parents were
4 generally unconcerned regarding DNA collection, with little awareness of controversies regarding the processing of
5 genetic material expressed by any ethnic group. Parents' primary concern in the parent study regarded potential
6 montelukast side effects.
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11
12 The findings suggest an absence of inter-ethnic discrepancies in motivating factors for research participation. All groups
13 were united in their anxieties regarding preschool wheeze and the need to find an effective treatment. Bangladeshi
14 parents were distinguished by a greater respect for medical opinion and a limited grasp of spoken and written English
15 which combined to increase their participation, but at the cost of limited understanding.
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20 21 *Strengths and limitations of the study*

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23 The study does not include parents who were unwilling to take part in the trial or take part in the qualitative interviews.
24 While recruitment of Bangladeshi participants to the parent study was good, perhaps because one of the research workers
25 was fluent in Bengali, it is clear (see Table 1) that participation of these parents in the qualitative interview study was less
26 common. This reluctance was perhaps related to concerns about coping with an interview conducted in English or with
27 the aid of an interpreter. Future qualitative studies of this sort may be able to overcome this reluctance by employing a
28 research worker fluent in the first language of potential respondents.
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36 *Comparison with existing literature*

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38 This study reinforces existing qualitative literature (24, 25) on recruitment to trials for children in general, and in the
39 consent process in particular (26) however the novel aspect of this study is the contrast between different ethnic groups,
40 especially in relation to understanding and accessible information. The difficulties some parents had in distinguishing
41 clinical treatment from research reflects previous reports,(8-11) while the finding about parental reassurance and sense of
42 control are in line with earlier work relating to consent by proxy.(7-11) Studies on lay understanding of the purpose of
43 genetic sampling have also found a lack of concern about this.(14, 15)
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51 *Implications for the conduct of research*

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53 We concur with the view that representative ethnic minority participation in trials is feasible if researchers take
54 appropriate steps to facilitate this. (5) It is clear that one of the stumbling blocks can be the provision of information in a
55 "user unfriendly" format. Modern ethics committees demand highly detailed PILs which may perversely reduce the
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1 quality of the consent decision by discouraging thorough reading and reducing assimilation of information.⁽²⁷⁾ This
2 observation is supported by current findings. As a matter for debate we suggest the introduction of a supplementary and
3 abbreviated PIL with a checklist of fundamental concepts to be covered during the informed consent process (this would
4 include the division between researcher and clinician roles). This document should be signed and a copy kept by both
5 researcher and study participant. The counter argument is that an abbreviated PIL would not fully inform parents,
6 however such a document (used alongside a detailed consent discussion) would add structure to and emphasise the
7 importance of the discussion and also serve as a palatable aide-memoire for participants. The full PIL could be retained
8 as a reference document. Approaches such as this may improve the quality and success of the consent process across the
9 ethno-social spectrum and their investigation should be an avenue for future study.
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Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:

Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

YOU MUST PROVIDE A RESPONSE FOR ALL ITEMS. ENTER N/A IF NOT APPLICABLE

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
<i>Personal Characteristics</i>		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	Dr V MacNeill page 7
2. Credentials	What were the researcher's credentials? E.g. PhD, MD PhD	PhD – author page
3. Occupation	What was their occupation at the time of the study?	Qualitative Health Research Fellow Author page
4. Gender	Was the researcher male or female?	Female [not reported] Can be deduced from authorship
5. Experience and training	What experience or training did the researcher have?	Previously Lecturer in research methods. Currently also Honorary Fellow in Health Services Research at City University London Previously Senior Research Scientist at U. of Oxford (10y) Experience reported on page 7
<i>Relationship with participants</i>		
6. Relationship established	Was a relationship established prior to study commencement? No	No – not reported
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Participants were informed that researchers sought to acquire a participant perspective on clinical trial conduct. Not reported in paper
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic Nil	Interests reported see page 7
Domain 2: study design		
<i>Theoretical framework</i>		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis,	Grounded theory reported see page 8

	ethnography, phenomenology, content analysis	
<i>Participant selection</i>		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Purposeful See page 7
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	email and telephone see page 7
12. Sample size	How many participants were in the study?	42 – see page 9
13. Non-participation	How many people refused to participate or dropped out? Reasons?	43 refusals & reasons see page 9
<i>Setting</i>		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Home – see page 7
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	Children/Translator See page 7
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Socio-economic and demographic data see pages 9 & 10
<i>Data collection</i>		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Interview topics summarized on page 7-8
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Audio – see page 7
20. Field notes	Were field notes made during and/or after the interview or focus group?	Yes see page 8
21. Duration	What was the duration of the interviews or focus group?	25-60 minutes see page 7
22. Data saturation	Was data saturation discussed?	Referred to on page 7
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No
Domain 3: analysis and findings		
<i>Data analysis</i>		
24. Number of data coders	How many data coders coded the data?	1 coder and 1 verifier – see page 8
25. Description of the coding tree	Did authors provide a description of the coding tree?	Described how derived see page 8
26. Derivation of themes	Were themes identified in advance or derived from the data?	Substantive topics identified in advance but themes derived from data see page 7-8
27. Software	What software, if applicable, was used to manage the data?	Nvivo9 see page 8
28. Participant checking	Did participants provide feedback on the findings?	No
<i>Reporting</i>		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant	Yes – throughout results section pages 12-22

	number	
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes see results pages 9-25
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes – all signposted in results section pages 12-22 and summarized on pages 23-25
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes – diverse case were a central feature throughout results section Pages 9-25 plus summary page 23-25

Once you have completed this checklist, please save a copy and upload it as part of your submission. When requested to do so as part of the upload process, please select the file type: *Checklist*. You will NOT be able to proceed with submission unless the checklist has been uploaded. Please DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.



Recruiting ethnic minority participants to a clinical trial: a qualitative study

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Recruiting ethnic minority participants to a clinical trial: a qualitative studyVirginia MacNeill¹, Chinedu Nwokoro¹, Chris Griffiths², Jonathan Grigg¹, Clive Seale²

¹Centre for Paediatrics, Blizard Institute, Barts and the London School of Medicine and Dentistry, Queen Mary, University of London, 4 Newark Street, London E1 2AT, UK

²Centre for Primary Care and Public Health, Blizard Institute, Barts and the London School of Medicine and Dentistry, Queen Mary, University of London, 58 Turner Street, London E1 2AB, UK

Correspondence to:

Dr Chinedu Nwokoro MBBChir MD

Centre for Paediatrics

Blizard Institute

4 Newark Street

London E1 2AT

Email: c.nwokoro@qmul.ac.uk

Telephone: 020 7882 2280

Fax: 020 7882 2195

Key words: asthma, child, ethnic groups, patient participation, clinical trials as topic

Word count (excluding title page, abstract, references, figures and tables but including quotation boxes): 4159

VM is a Qualitative Health Research Fellow

CN is a Respiratory Paediatrician and Clinical Research Fellow

CG is a General Practitioner and Professor of Primary Care

JG is a Paediatrician and Professor of Paediatric Respiratory Medicine

CS is a Professor of Medical Sociology

Contributorship

VM carried out the interviews, analysed data and wrote the initial draft of the paper. JG led the original research bid; CG and CS were co-applicants. CS supervised VM's data collection and analysis. JG, CG and CN contributed to the drafting of the paper. CS is guarantor.

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Competing Interests

There are no competing interests.

Data Sharing Statement

Consent for publication of raw data obtained from study participants. Original transcripts are available from the corresponding author on request.

Licence Statement

I Dr Chinedu Nwokoro the Corresponding Author of this article contained within the original manuscript which includes any diagrams & photographs, other illustrative material, video, film or any other material howsoever submitted by the Contributor(s) at any time and related to the Contribution ("the Contribution") have the right to grant on behalf of all authors and do grant on behalf of all authors, a licence to the BMJ Publishing Group Ltd and its licensees, to permit this Contribution (if accepted) to be published in BMJ Open and any other BMJ Group products and to exploit all subsidiary rights, as set out in the licence at: (http://group.bmj.com/products/journals/instructions-for-authors/BMJOpen_licence.pdf)

Abstract**Objectives:**

To compare the motives and experiences of different ethnic groups participating in a randomised double blind placebo-controlled trial of montelukast in preschool wheeze, and to assess parents' or guardians' understanding of trial procedures and their implications, including the collection of genetic material.

Design:

Qualitative interviews with parents or guardians.

Setting:

Interviews occurred in the homes of London children recruited to a national multicentre clinical trial following primary and secondary care attendance with wheeze.

Participants:

42 parents (20 of Bangladeshi origin, 10 white UK, 12 other ethnicities) of preschool children enrolled in a clinical trial.

Results:

Bangladeshi families were relatively reluctant to participate in the qualitative study, despite strong engagement with the parent study.

Anxiety related to wheezing was a common primary motive for trial enrolment. Parents viewed the trial as a route to improved treatment. Verbal delivery of trial information appeared more effective than study literature, especially for Bangladeshi families, with low parental literacy and high levels of trust in medical professionals potential contributors to this effect. All ethnic groups expressed a low understanding and/or retention of essential study concepts such as randomisation and genetic testing.

Conclusions:

Bangladeshi families are particularly motivated to participate in clinical trials despite variable comprehension of study concepts. This motivation is more strongly contingent on strong researcher-subject rapport than on the quality of study literature. Trial teams seeking to recruit from South Asian populations should emphasise face-to-face verbal explanation of trial concepts and procedures and consider modified trial literature.

Article Summary

Article Focus:

- South Asians and ethnic minorities are underrepresented in clinical trials, affecting applicability of results.
- South Asian group representatives suggest that a personal approach by researchers may improve recruitment.
- Parents enrolling young children in trials often have poor understanding of the implications of consent, whether this varies across ethnic groups is unknown.

Key Messages:

- Self-interest as well as altruism influence parental decision to enrol in a paediatric respiratory clinical trial.
- Decision to enrol is influenced more by trust in the research team than by written information.
- Careful verbal explanations of trial procedures, advantages and disadvantages are particularly important for parents of Bangladeshi origin.

Strengths and Limitations:

- Data from a study population historically difficult to engage in quantitative or qualitative clinical research.
- The sample size is small but adequate to achieve data saturation.
- There is an absence of data on parents declining to participate in the parent study.

Introduction

Background

The under-representation of South Asians and other ethnic minority groups in clinical trials affects the generalisability of study findings and ultimately contributes to inequities in access to health care.(1, 2) Marked ethnic disparities exist in asthma outcomes(3) and ethnically delineated barriers to participation in trials concerning asthma interventions have been identified. These include a residual stigma attached to the asthmatic label, anxieties related to understanding the implications of participation, worries about the effects of trial medications, as well as cost and time concerns.(4) Suggested solutions include: provision of incentives, use of multilingual trial literature, employment of personal approaches and addressing researchers' reluctance to invite participation from the full cultural and linguistic spectrum.(4-6)

Currently there is poor understanding of the perspective of ethnic minority parents involved in paediatric clinical trials. Previous work has explored the role of parents as responsible decision makers co-reliant on the researchers and research governance procedures for guidance and protection.(7) Significant elements include parents' poor comprehension of the trial process,(8) the parental emotional turmoil related to paediatric illness, and confusion born of the blurring of ethical boundaries between clinical and research practice.(9-11)

Parent Study

The current study is embedded within a randomised controlled trial (the parent study) of the genetic determinants of the efficacy of intermittent montelukast in preschool wheeze and provides an opportunity to investigate the perspectives of the parents of trial participants. It was hypothesised that a genetically determined subgroup of patients (with higher urinary inflammatory mediators) would respond better to montelukast (have reduced USMA) than their peers.

Qualitative Study

Preschool wheeze (PSW) is a common but poorly understood disease of early childhood equally prevalent in UK children of South Asian and European origin.(12) The ethnically diverse setting of the recruiting institution permits the principal aim of this study which is to compare attitudes and experiences of participating families across ethnic groups, including a significant number of participants of South Asian (Bangladeshi) origin. A secondary aim arises from the fact that both positive and negative public perceptions of pharmacogenetics exist.(13) A recent focus group study involving diverse ethnic minority participants in biobank research found generally positive attitudes, with participation driven by

1 perceptions of personal or collective benefit, despite limited understanding of genetics.(14, 15) Hence this work aims to
2 describe ethnic variation in participants' understanding of the genetic element of the trial.
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6 **Methods**

7 *Parent study procedures*

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10 Preschool children with a history of wheezing were recruited by a small team of children's research nurses and secondary
11 care paediatricians following hospital attendance for wheeze, or after receiving information from their primary care
12 physician. For hospital attendees, recruitment occurred immediately prior to or shortly after discharge from hospital.
13 Families received a trial information pack and subsequently discussed the study with the research team. Written and real-
14 time verbal Bengali translation was available as required. Amenable parents then gave written informed consent (to
15 paediatrician, research nurse, or both) after which a mouth swab (for leukotriene-pathway genes) and urine sample (for
16 leukotriene levels) were collected. Parents agreed to administer a ten day course of oral medication (randomly allocated
17 to montelukast or placebo) at the onset of a cold or wheezing symptoms, and to complete a daily diary record for the
18 same period. They also received progress calls from the clinical research team at regular intervals and were encouraged
19 to phone if they had any queries or concerns. Children were followed up for one year and the need for unscheduled
20 respiratory medical attendance assessed. The qualitative study (QS) was based at the East London host centre of this
21 multicentre trial and involved an audio-recorded semi-structured interview with parents of enrolled children.
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34 *Participant recruitment*

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36 All participants in the trial and the qualitative sub-study received written information about the study at recruitment. 139
37 parents gave formal written consent for their child to be enrolled in the trial and 85 of these parents gave written consent
38 to a qualitative interview at the same time (Table 2). The initial plan was to sample purposefully from the 85 consenting
39 parents, aiming for maximum variation (16) in terms of ethnicity, gender and other variables and then theoretically,
40 according to iterative analysis of initial interviews.
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47 *Data generation*

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49 Individual interviews were considered the most appropriate method for data collection as this ensured confidentiality. A
50 semi-structured interview guide (Box 1) for the interviews was developed following a literature review and discussions
51 between VM and CS (4, 7, 17, 18). Interviews were conducted by VM, an experienced non-clinical qualitative researcher
52 with an interest in the development of healthcare services in partnership with the patient population. Each interview took
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1 place in the parent's home and lasted 25-60 minutes. Preschool children were present in many instances. Interviews were
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3 conducted in English except one interview which required the assistance of a Bengali interpreter.
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5 **Box 1: Topics included in the semi-structured interview guide**

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8 1. Family and child background information
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 - 10 • Child's history of wheeze
 - 11 • Treatment and diagnosis
 - 12 • Impact on child/parents/family

13 2. Parents experiences of joining the trial
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 - 15 • Motivations
 - 16 • Consent and research governance processes
 - 17 • Attitudes towards the collection of DNA and genetically guided therapy

18 3. Parents attitudes to and experiences of giving the trial drug to their child.
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25 **Data analysis**

26 Interviews were audio-recorded and professionally transcribed verbatim. CS also reviewed a sample of interview
27 transcripts during the course of the data collection period. Transcripts and field notes were imported into NVivo9, a
28 qualitative data analysis programme (20). VM and CS developed a coding framework that drew on the research
29 questions, previous research about patient experiences of taking part in clinical trials and themes that emerged in the
30 course of the analysis. The data were systematically coded and analysed, using a modified grounded theory approach
31 (21) incorporating the constant comparison technique to elicit key themes and explore deviant cases (22, 23)
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40 **Ethics**

41 The study was reviewed and granted approval by the South East Research Ethics Committee (09/H1102/110). Written
42 informed consent for QS was included as part of the parent study consent process and reconfirmed immediately before
43 the qualitative interviews took place. The QS adhered to the RAT qualitative research review guidelines (24)
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49 **Results**

50 Of the 85 parents who gave written consent to structured interview at parent study enrolment only half subsequently
51 participated in a face to face interview. The reasons for non-participation are as stated in Table 1. The remaining 42
52 parents agreed to a face to face interview, which took place over a seven month period. There is no ideal sample size for
53 qualitative studies (19) and this was a sufficient number of interviews within this opportunist sample to achieve data
54 saturation.
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Table 1: Reasons given for decline or no response to request for qualitative interview

Reasons given for decline or no response to request for qualitative interview	Number of parents
No response	14
Declined – no reason given	11
Declined – no time (employment-related)	4
Declined – unable to speak English	5
Declined – no time (heavily pregnant or caring for newborn)	4
Declined – annual or religious or imminent extended holiday	5
Total number of parents	43

At QS commencement 139 families had consented to study enrolment; Bangladeshi participants were relatively overrepresented in the parent study and white British underrepresented. Bangladeshi parents taking part in the parent study were less likely than parents of ‘other’ ethnicity to be interviewed for the study reported here. Table 2 shows ethnically delineated differences in study participation.

Table 2: Patterns of participation by ethnic group (25)

	Bangladeshi	White British	Other**	Total
Percentage of Local <15 Population by ethnic group*	22,200 (50%)	14,500 (33%)	7,500 (17%)	44,200 (100%)
Parents with children enrolled in Parent Study at time of QS	94 (68%)	24 (17%)	21 (15%)	139 (100%)
Parents consenting to QS at time of enrolment to Parent Study (% of parents enrolled, 95% CI)	48 (51%, 41-61)	17 (71%, 51-85)	20 (95%, 76-100)	85
Qualitative interview completed (% of parents enrolled, 95% CI)	20 (21%, 14-31)	10 (42%, 24-61)	12 (57%, 37-76)	42

*There is no information available regarding ethnicity of the local under 5 population. Data regarding under-15 children is deemed an appropriate surrogate given that the overwhelming majority of local pre-schoolers survive to their teens and there is no evidence of an ethnically divergent change in local birth rates in recent years.

**Other interviewed parents: Africa (n=6), Caribbean (n=2), South America (n=1), Middle East (n=1), China (n=1)

We proceed to outline the characteristics of participants, then report on the themes that emerged from the interviews.

These include:

1. Reasons parents gave for enrolling their child in the trial,
2. Participating parents' experience of the consent process and understanding of written and verbal information provided at the outset of the trial, in particular their understanding of the randomisation process,
3. Participating parents' understanding and response to the collection of genetic information.
4. The nature of participating parents' consultations with other people before deciding to take part.

Throughout, we report on differences and similarities between Bangladeshi and other participants.

Characteristics of participants

Table 3: Characteristics of qualitative interview participants

		Bangladeshi	White UK	Other
Demographics				
Male		6	2	2
Female		14	8	10
Age in years (mean (SD))		35 (7.8)	34 (6.2)	36 (4.3)
Language				
1st Language	Bengali/Sylheti	19		
	English	1	10	4
	French			2
	Arabic			2
	Mandarin			1
	Creole			1
	Portuguese			2
Fluency in spoken English*	Excellent	5	10	4
	Good	1	0	0
	Fair	5	0	5
	Poor	9	0	3
Socioeconomic				
Educational attainment	Left before 16 years	1		
	GCSE or equivalent	8	6	3
	A level or equivalent	1	0	3

	Graduate degree	1	4	3
	Postgraduate degree	1		2
	Not answered	8		1
Occupation of highest earner in family	Higher managerial, administrative & professional	1	2	2
	Intermediate	3	1	3
	Routine and manual	8	2	3
	Student			1
	Not answered	8	5	3
	Total	20	10	12

* Interviewer's judgement

The majority of respondents were female. Bangladeshi participants had poorer spoken English than other groups and were less inclined to disclose their level of schooling, perhaps indicating sensitivity regarding poor educational attainment. Most households reported at least one working parent, but the numbers engaged in full time, part time, or shift work were unclear due to guarded responses.

Parents of children in all groups reported anxiety related to their helplessness during wheezing attacks, often driven by the first hospital presentation. Major fears were of the potential for death or major long term disability. These concerns drove a preoccupation with monitoring their child's health, together with anxiety about the potential progression of a cold to a wheeze with the attendant hospital visit, investigations and treatment. These fears were important drivers for trial participation, with hopes that participation might contribute to improved treatment for wheeze. Box 2 shows interview extracts relevant to this theme.

Box 2: Anxieties about wheeze in children

When I am putting him in the shower he was difficult to breath, he goes (makes gasping sound) with his hand in his mouth and I was scared and then I had to call an ambulance...he stayed in hospital for two days.(24F-Brazilian)

He wasn't too good they said we have to keep him in and he had oxygen up his nose. It was horrible. So he was in hospital for three days. That was the worst three days of my life. (41F-UK)

I'm so worried. My God. I know asthma may kill so I'm very worried (01F-Bangladeshi)

'My worst fear was that if I'm not with him or something like that....not breathe or...I don't know, I don't know much about asthma. I don't want him to get that. (08F-Egyptian)

'I can remember saying to (husband) very clearly if he dies don't come and collect me because I don't want to leave without him' (19F-Caribbean)

'I really didn't know how bad it was and how it can affect a child. And I really didn't know it was going to be the start of this long process of hospital after hospital after hospital.' (09F-UK)

'I am looking for a final treatment for her because this disease is not good for her health you know so I am looking for much better treatment for her and to find a treatment which is better for her whole life.' (33FM-Bangladeshi).

1 This was the emotional context within which parents were approached by the clinical trial team and asked if they would
2 consider enrolling their child into the parent study. Parents reported being approached while inpatients or during follow-
3 up appointments in primary or secondary care. Most children were already on prescribed medication for wheeze.
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8 Half of the parents (11/20 Bangladeshi, 6/10 UK, 4/12 other) said that their primary reason for enrolling their child was
9 that they hoped it would benefit their child in curtailing or curing the wheeze. A subset of these believed that the trial
10 medicine represented an individual treatment regime for their child, perhaps conflating research with personal treatment.
11
12 Others also viewed it as a route to additional information, treatments and medical attention by skilled physicians (Box 3).
13
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16
17 A third (15/42, of which 5/20 Bangladeshi, 4/10 UK, 6/12 other) said that their aim was to help other children by
18 contributing to the advancement of medical knowledge (although benefit to others was secondary to a consideration of
19 potential benefit to their own child). Only four parents (2/10 UK, 2/12 other) voiced a wholly altruistic outlook by
20 pointing out that the results of the trial would be unlikely to benefit their own child.
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27 A few parents (2/20 Bangladeshi, 1/10 UK, 0/12 other) based their decision to participate in the trial primarily on their
28 trust in the research team, these families appeared not to differentiate between trial researcher and healthcare provider
29 roles. Parents felt reassured that they could opt out of the trial at any time and, particularly if their child experienced side
30 effects.
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Box 3: Other reasons for taking part*Benefit to child*

I wanted to see if it helps my daughter, to see if it got rid of her wheeze. (42F-Bangladeshi)

They said if you do this study your daughter is going to get better. (25F-Bangladeshi)

It's an extra medicine for my daughter that will help her, and it helps her stay at home rather than going to the GP or hospital all the time. (42F-Bangladeshi)

A very good way of you know, getting him seen by good doctors ... and hopefully getting answers you're looking for' (05F-UK)

Benefit to others

[My child] won't really benefit but from it ...this is obviously a trial so that they can try and prescribe this medicine in the future for children. (29F-UK)

It's good for the future. All children. Not for her [child] because she has already got it now, but yes, all children of the world. (40F-African)

Hopefully it's good for other children and good for her. (6M-Chinese)

Trust in clinicians

I thought like, you know, it's from hospital, obvious it's good for him. So the doctor knows better than us. (02F-Bangladeshi)

Being in control

It's reassuring that they kept saying that at any time we can pull out. (21F-Bangladeshi)

They explained to me that the main side effect was sleep like sleep disturbance erm... and obviously if it was too much then just stop. (04F-UK)

Beliefs about the acceptability to their child and the effects of the substance they were given – whether montelukast or placebo - were clearly important motives in maintaining or discouraging continuing participation (Box 4). 4/20 Bangladeshi parents (but no others) believed there would be no side effects, reporting that this was what the trial researcher had told them. Even parents with a well-informed understanding of the trial process said they would consider withdrawing their child if they believed the medication was not having a beneficial effect. Three (one from each ethnic group) had already decided to discontinue, because their child did not like the medication or because it did not appear to

1 be effective, or because of perceived adverse effects. Three more (2/10 UK, 1/12 other) said they would consider
 2 dropping out for similar reasons if they believed that their child had been allocated the placebo drug, or if the medication
 3 seemed ineffective or harmful, indicating that subject recruitment and retention is driven strongly by the perceived
 4 likelihood of personal benefit.
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 9 **Box 4: Effects and acceptability of medication**

10 They just told me there's not going to be there, there is no side effects at all. (23M-Bangladeshi)

11
 12 Yes medicine he doesn't like. (22F- Bangladeshi)

13
 14
 15 I don't want there to be any side effects. Yes everything has got side effects but, it's the sleeping part and the
 16 behaviour that was another thing. I didn't want that to change. (41F-UK)

17
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 19 I think our first step would be if I thought he wasn't on the medicine, getting the medicine prescribed somewhere
 20 else. (05F-UK)

21
 22
 23 I mean the only reason I would come out of the trial was if I thought there was any erm... negative side effects. And
 24 we're now on our second dose of medicine and he's been totally fine. (10F-UK)

25
 26
 27 I'd go back to the hospital...and tell them the medicine you give to me maybe don't do anything. (07F-African)

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 30 The wheezing is still there and it was not going away, so I just said, I just stopped giving to him, I said I didn't
 31 think it was helping him at all. (32F-Caribbean)

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 37 *Information and consent*

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 39 **Table 4: Information and Consent**

	Bangladeshi	White UK	Other*	Total
Satisfied with initial information	20 (100%)	10 (100%)	12 (100%)	42/42 (100%)
Personally Read PIL	11/20 (55%)	6/10 (60%)	4/12 (33%)	21/42 (50%)
Had PIL read to them	5/20 (25%)	4/10 (40%)	6/12 (50%)	15/42 (36%)
Understanding of randomisation	5/20 (25%)	7/10 (70%)	3/12 (25%)	14/42 (33%)
Awareness that DNA sample taken	6/20 (30%)	9/10 (90%)	9/12 (75%)	24/42 (57%)

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 54 All parents reported satisfaction with the initial trial information they had received and that all queries were answered
 55 adequately. Retention was poor however, and by the time of the interview few could recall significant detail. The
 56 decision to consent was strongly influenced by the meeting with the clinical team.
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2
3 The patient information leaflet (PIL) was translated from English into Bengali but not into other languages as
4 Bangladeshis are by far the largest local non-English speaking minority, with a disproportionately reduced likelihood of
5 English literacy in comparison to other, rarer language groups (Table 3). Interviewees were often evasive regarding their
6 reading of the PIL, suggesting that this was an area of sensitivity for some respondents. Just 7 (41%) of 17 Bangladeshi
7 respondents who gave direct answers claimed to have read the leaflet (compared with 15/16 (93%) of non-Bangladeshi);
8 a further 7 said they had not and three said that other family members had read it for them. Box 5 shows comments made
9 about the PIL. The length and detail of the PIL appeared to discourage reading in some (mainly Bangladeshi)
10 respondents, placing the emphasis more firmly on personal interaction with researchers for communication of trial
11 information.
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20 **Box 5: Comments about the patient information leaflet**

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22 Lots of pages. Yeah, little bit I read...He explained me nicely that time. I understand what he's saying but I can't
23 tell you now. I can't remember all of it. (01F- Bangladeshi)

24
25
26 Some of the first page and second page we did and then we was happy with this. We read we are so happy some of
27 the paragraphs is very nice but it carried on and on. (15M- Bangladeshi)

28
29
30 That time I was very busy and I don't have time to read it, and when I had time I forgot. (25F- Bangladeshi)

31
32 I understood what she explained so I didn't really bother to read that much. (38F-Bangladeshi)

33
34 Yes of course, I read everything. Erm, I did read it, I could have read more, erm but I am one of the people who
35 reads everything. I am used to reading complicated stuff in my work anyway. (30M-UK)

36
37 They were good explanatory, there was a lot of them but it's not the same as talking to somebody saying well look
38 I'm worried about and then they'll they put me right. I had a better understanding and you can't ask a question on a
39 bit of paper. (09F-UK)

40
41 It told me everything I need to know to be able to start the trial. (27F-Black UK)

42
43 Er....can't remember. Something. I have to think... because it was a long time ago. (08F-Egyptian)

44
45 I read it, well both myself and my partner read it and we did find it like yeah it was absolutely fine for us. (19F
46 Caribbean)

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48 I read it....Just first the introduction, the introduction this research. (06M-Chinese)
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Understanding the research process

Just over a third of parents understood the principle of randomisation to some degree (5/20 Bangladeshi, 7/10 White UK, 3/12 Others). (see Box 6) Bangladeshi families were least aware that a DNA sample had been taken from their child (6/20 Bangladeshi were aware, 9/10 UK, 9/12 Others). Despite poor comprehension of personalised medicine and genetic testing concepts most respondents viewed the genetic component of the study positively.

Box 6: Understanding and acceptance of randomisation and DNA component

Randomisation

I totally don't know if the powder is the ..er..blank one (06M-Chinese)

Well they said they were going to test so many people with this and so many people with that and then get the results and see what. 17F-Bangladeshi)

We are in a trial and we could be given a placebo or cure and that's done on a group of kids. (26M-Middle Eastern)

Yes, so I could have a treatment that is sherbet in other words. (27F-Black UK)

DNA component

They did tell me [its purpose] at the time but I really can't remember. (21F- Bangladeshi)

They told me, eh, I can't remember, sorry. (39F-African)

It's only if it didn't hurt him, it was only a swab from his mouth so no, that was fine. (04F-UK)

As long as it's not invasive (08F-Egyptian)

I'm sure it's only used for the medical and not generally. I think the only time it would be concerning is like I said if they were going to share the information. (21F- Bangladeshi)

I haven't really thought about it. It's just part of the one part of the study that needs to be that they're looking at. I don't think there's anything sinister being done. Everyone's going to end up on a DNA database somewhere. (05F-UK)

Consulting others

1 There were some differences between ethnic groups in how decisions were made to enrol their child in the trial. Some
2 decided to consent as soon as they were approached but others sought advice from other people. Some (4/20)
3 Bangladeshi respondents reported that they relied entirely on the medical profession to guide them but they were the only
4 group to express this. Some non-Bangladeshi respondents were able to call on medically qualified family members for
5 their advice or made use of the internet and other sources of pharmaceutical information. Very few respondents (3/42),
6 all of White UK ethnicity, reported receiving negative views about the trial from family or friends. Box 7 shows relevant
7 extracts.
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14 **Box 7: Other sources of information and reassurance**

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17 It's from hospital obvious it's good for him. He...the doctor knows better than us. (02F- Bangladeshi)

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20 I told him [my husband] and he said OK if you want to go you can go. (25F- Bangladeshi)

21
22
23 I looked at the internet I think.....where I work we've got an old copy of the BNF so I looked at that. (18M-UK)

24
25
26 I was pretty certain I think.. but his dad was a bit more reluctant because he's sort of thought it was a trial
27 medicine.... and then when I explained that montelukast was already a drug... and if he has asthma and it gets
28 progressively worse, there's a good chance it will be prescribed anyway, so.., (10F-UK)
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33 **Discussion**

34 *Summary of the main findings*

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36 A major reason for parents agreeing to enrol their child in the trial related to their previous experiences of witnessing
37 their child having severe wheeze attacks. This caused anxiety in many parents, regardless of ethnicity, motivating them to
38 find an effective treatment. However some parents found it difficult to distinguish between clinical treatment and
39 research despite receiving information about the trial processes, including randomisation and the use of a placebo.
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46 A second reason for enrolment was the reassurance parents received that they would retain control, not only regarding
47 remaining in the study, but also regarding whether and when they gave their child the study medicine.
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51 Thirdly, most parents had confidence in the research team and preferred face to face meetings with the clinical trial
52 researchers to reliance on written patient information leaflets (PILs). They could ask questions directly of the research
53 team and found the prescribed and formalised information sheets too long. While none said that they had received too
54 much information about the trial, few had read beyond the first few pages. It appears that verbal delivery of trial
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1 information was more important than study literature. Bangladeshi families demonstrated poor familiarity with essential
2 trial concepts at interview (Table 4), however it is unclear whether this reflects poor initial understanding or poor
3 information retention. All parents report being satisfied with the information received at recruitment, however although
4 similar numbers of white and Bangladeshi parents claim to have read the PIL (Table 4), the information density of the
5 PIL may have prevented complete reading (Box 5), or rereading when details had faded from memory. The
6 disproportionate effect on Bangladeshi families may relate to the large number of non-responders to the query regarding
7 educational attainment (Table 3), where non-response may indicate a low educational level. Despite this poor
8 information level, Bangladeshi parents were overrepresented in the parent study, reflecting a desire to participate that was
9 likely influenced by researcher rapport (Box 3, Box 5) (with a Bengali-speaking team member), a linguistic benefit that
10 was lost in the translated PIL due to low literacy. Hence parents gave informed consent but lacked a *useful* written
11 record of the details to which they had agreed.
12
13

14 The study found a lack of curiosity about research processes and practices amongst all ethnic groups. Parents were
15 generally unconcerned regarding DNA collection, with little awareness of controversies regarding the processing of
16 genetic material expressed by any ethnic group. Parents' primary concern in the parent study regarded potential
17 montelukast side effects.
18
19

20 The findings suggest an absence of inter-ethnic discrepancies in motivating factors for research participation. All groups
21 were united in their anxieties regarding preschool wheeze and the need to find an effective treatment. Bangladeshi
22 parents were distinguished by a greater respect for medical opinion and a limited grasp of spoken and written English
23 which combined to increase their participation, but at the cost of limited understanding.
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25

26 *Strengths and limitations of the study*

27 The study does not include parents who were unwilling to take part in the trial or take part in the qualitative interviews.
28 While recruitment of Bangladeshi participants to the parent study was good, perhaps because one of the research workers
29 was fluent in Bengali, it is clear (see Table 2) that participation of these parents in the qualitative interview study was less
30 common. This reluctance was perhaps related to concerns about coping with an interview conducted in English or with
31 the aid of an interpreter. Future qualitative studies of this sort may be able to overcome this reluctance by employing a
32 research worker fluent in the first language of potential respondents.
33
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35 *Comparison with existing literature*

1 This study reinforces existing qualitative literature (26, 27) on recruitment to trials for children in general, and in the
2 consent process in particular (28) however the novel aspect of this study is the contrast between different ethnic groups,
3 especially in relation to understanding and accessible information. The difficulty some parents had in distinguishing
4 clinical treatment from research reflects previous reports,(8-11) while the finding about parental reassurance and sense of
5 control are in line with earlier work relating to consent by proxy.(7-11) Studies on lay understanding of the purpose of
6 genetic sampling have also found a lack of concern about this.(14, 15)
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12 13 14 *Implications for the conduct of research*

15 We concur with the view that representative ethnic minority participation in trials is feasible if researchers take
16 appropriate steps to facilitate this. (5) It is clear that one of the stumbling blocks can be the provision of information in a
17 “user unfriendly” format. Modern ethics committees demand highly detailed PILs which may perversely reduce the
18 quality of the consent decision by discouraging thorough reading and reducing assimilation of information.(29) This
19 observation is supported by current findings. As a matter for debate we suggest the introduction of a supplementary and
20 abbreviated PIL with a checklist of fundamental concepts to be covered during the informed consent process (this would
21 include the division between researcher and clinician roles). This document should be signed and a copy kept by both
22 researcher and study participant. The counter argument is that an abbreviated PIL would not fully inform parents,
23 however such a document (used alongside a detailed consent discussion) would add structure to and emphasise the
24 importance of the discussion and also serve as a palatable aide-memoire for participants. The full PIL could be retained
25 as a detailed reference document for parents. Approaches such as this may improve the quality and success of the
26 consent process across the ethno-social spectrum and their investigation should be an avenue for future study.
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Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:

Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

YOU MUST PROVIDE A RESPONSE FOR ALL ITEMS. ENTER N/A IF NOT APPLICABLE

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
<i>Personal Characteristics</i>		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	Dr V MacNeill page 7
2. Credentials	What were the researcher's credentials? E.g. PhD, MD PhD	PhD – author page
3. Occupation	What was their occupation at the time of the study?	Qualitative Health Research Fellow Author page
4. Gender	Was the researcher male or female?	Female [not reported] Can be deduced from authorship
5. Experience and training	What experience or training did the researcher have?	Previously Lecturer in research methods. Currently also Honorary Fellow in Health Services Research at City University London Previously Senior Research Scientist at U. of Oxford (10y) Experience reported on page 7
<i>Relationship with participants</i>		
6. Relationship established	Was a relationship established prior to study commencement? No	No – not reported
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Participants were informed that researchers sought to acquire a participant perspective on clinical trial conduct. Not reported in paper
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic Nil	Interests reported see page 7
Domain 2: study design		
<i>Theoretical framework</i>		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis,	Grounded theory reported see page 8

	ethnography, phenomenology, content analysis	
<i>Participant selection</i>		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Purposeful See page 7
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	email and telephone see page 7
12. Sample size	How many participants were in the study?	42 – see page 9
13. Non-participation	How many people refused to participate or dropped out? Reasons?	43 refusals & reasons see page 9
<i>Setting</i>		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Home – see page 7
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	Children/Translator See page 7
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Socio-economic and demographic data see pages 9 & 10
<i>Data collection</i>		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Interview topics summarized on page 7-8
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Audio – see page 7
20. Field notes	Were field notes made during and/or after the interview or focus group?	Yes see page 8
21. Duration	What was the duration of the interviews or focus group?	25-60 minutes see page 7
22. Data saturation	Was data saturation discussed?	Referred to on page 7
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No
Domain 3: analysis and findings		
<i>Data analysis</i>		
24. Number of data coders	How many data coders coded the data?	1 coder and 1 verifier – see page 8
25. Description of the coding tree	Did authors provide a description of the coding tree?	Described how derived see page 8
26. Derivation of themes	Were themes identified in advance or derived from the data?	Substantive topics identified in advance but themes derived from data see page 7-8
27. Software	What software, if applicable, was used to manage the data?	Nvivo9 see page 8
28. Participant checking	Did participants provide feedback on the findings?	No
<i>Reporting</i>		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant	Yes – throughout results section pages 12-22

	number	
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes see results pages 9-25
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes – all signposted in results section pages 12-22 and summarized on pages 23-25
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes – diverse case were a central feature throughout results section Pages 9-25 plus summary page 23-25

Once you have completed this checklist, please save a copy and upload it as part of your submission. When requested to do so as part of the upload process, please select the file type: *Checklist*. You will NOT be able to proceed with submission unless the checklist has been uploaded. Please DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.