An exploration of patients' experiences of participation in a randomised controlled trial of the Manchester Acute Coronary Syndromes (MACS) decision rule

SHORT TITLE:

Exploration of patients' experiences in the MACS trial

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Declarations

Richard Body has previously undertaken research involving donation of reagents without charge by Roche, Abbott, Alere, Siemens and Randox. Richard Body has accepted the provision of economy class travel and accommodation to present findings unrelated to this work at two Roche-sponsored conferences and at a scientific session sponsored by Randox.

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Abstract

Background

As an important part of a pilot study to determine the feasibility of a large randomised controlled trial (RCT) comparing use of the Manchester Acute Coronary Syndromes (MACS) decision rule to standard care, we aimed to explore patient attitudes and potential barriers to participation in a trial of this nature.

Methods

We conducted a qualitative study nested within a pilot RCT comparing use of the MACS rule (which could enable some patients with chest pain to be discharged earlier) to standard care. Semi-structured interviews with consenting participants were conducted with reference to a bespoke topic guide. Interviews were audio recorded, transcribed verbatim and analysed using the Framework method with an inductive approach.

Results

The ten interviewees expressed that participation in the trial was generally acceptable. All but one recommended participation to others. Participants who were in pain or anxious at the time of arrival reported that the initial invitation to participate in the trial was sometimes made too early. The approach was welcome providing they had been given time to settle. Interviewees welcomed the opportunity that trial participation offered for them to play a more active role in their healthcare and to reduce unnecessary waiting time. Participants appeared to like that participation in the trial might mean they could return home sooner and welcomed the provision of follow-up. Although several participants described being generally sceptical of medical research, they were amenable to participation in this trial. This appears to be because they agreed with the need for research in this field and perceived the intervention as non-invasive.

Conclusions

Patients were positive about their participation in this RCT comparing the MACS rule to standard care. A number of areas for improving trial design were identified and should be considered in the planning of future large trials.

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Abbreviations used in this manuscript

MACS	Manchester Acute Coronary Syndromes
ED	Emergency Department
RCT	Randomised controlled trial
ACS	Acute Coronary Syndromes
ECG	Electrocardiogram
hs-cTnT	High sensitivity cardiac troponin T
H-FABP	Heart-type fatty acid binding protein

What this study is about

The Manchester Acute Coronary Syndromes (MACS) decision rule has been shown to risk stratify patients presenting with chest pain to the Emergency Department, potentially reducing unnecessary hospital admissions. Evaluation of the patients perspective before engaging on a full randomised controlled trial is essential to determine patient-perceived acceptability and identify weaknesses in the trial design.

What this study adds

Our analysis suggests that patients were positive about participation in this randomised controlled trial. However several areas of improvement for future large trials have been identified.

Background

Conducting research in emergency settings is notoriously challenging, particularly when it involves evaluation of a time critical, complex intervention. Participants must rapidly digest information and make important decisions about their participation in the study while in the midst of a suspected medical emergency. Recruiting enough patients in a timely fashion is a common difficulty in clinical trials. Despite the difficulties relatively little remains known about the patient's perspective.[1,2] We recently completed a pilot randomised controlled trial, which aimed to evaluate the feasibility of a definitive trial of such an intervention.

The Manchester Acute Coronary Syndromes (MACS) clinical decision rule is a computer-based model that has been shown to identify patients presenting to the Emergency Department (ED) with suspected acute coronary syndromes (ACS), who could safely be discharged following a single blood test.[3,4]

As an important component of a pilot study designed to evaluate the feasibility of a randomised controlled trial (RCT) comparing use of the MACS rule to standard care, we conducted a qualitative study aiming to explore the acceptability of participation in this trial from a patient's perspective to primarily guide improvement of the trial design. Secondarily, this qualitative study aimed to explore patient experiences in a RCT of this nature in the emergency setting in general.

Methods

This qualitative study was nested in a pilot randomised controlled trial comparing use of the MACS decision rule to standard care. We included consenting adults aged ≥ 18 years presenting with suspected ACS to one of the two participating trial centres (Manchester Royal Infirmary). This study

was approved by the Greater Manchester Central Research Ethics Committee (reference 13/NW/0081).

The trial intervention had to be completed within 4 hours of arriving in the ED, so patients were approached on arrival and asked to give initial verbal consent to participate in the trial by either a research nurse during office hours or a GCP-trained physician. They were then provided with a patient information sheet and given time to further consider participation before consenting in writing. Those who provided written informed consent were then randomly allocated to either the control group (which received standard care according to contemporary guidelines) or the intervention group (which received care guided by the MACS decision rule and who may therefore have been identified as eligible for immediate discharge following a single blood test). Participants were followed up by telephone for the primary outcome (successful discharge within 4 hours of arrival without an incident major adverse cardiac event) after 30 days. Patients eligible for early discharge in the MACS pilot trial were asked to return for a follow-up blood test they otherwise would have had during their hospital admission. This element of the trial design had been suggested as an extra safeguard by a service user group, which we consulted in the design phase.

A total of 283 patients had been screened initially with 145 not meeting inclusion criteria and seven (2.5%) declining consent. There were 131 patients included in the MACS pilot trial with a mean age of 58.9 years (SD 16.3). Participants were 40% female and a majority of 66% had White British ethnic origin, followed by 9% Asian Pakistani. Of the patients in the intervention arm 16 (24%) were eligible for early discharge according to the MACS rule. All 131 patients who participated in the pilot trial were also asked to provide written informed consent to participate in this qualitative study. We aimed to purposively sample consenting participants to maximise heterogeneity (according to age,

sex, ethnic origin and MACS risk group). Those participants were then offered an appointment at a mutually convenient time.

Between 3/2014 and 5/2014, semi-structured interviews were conducted by one of two interviewers. Nine interviews were conducted by HA (a nephrologist who was otherwise independent of the trial) and one was conducted by RB (emergency physician and principal investigator of the MACS pilot trial). Interviews took place 3 to 6 months after initial patient presentation to the ED using a bespoke topic guide (see Supplementary Appendix). To maximise engagement, either daytime or evening interviews were available on either the telephone or in person at a Clinical Research Facility adjacent to the hospital. The interviews were audio recorded and transcribed verbatim.

We analysed the data using Framework, a well described and accepted methodology suitable for qualitative health services research.[5] The analysis consisted of seven phases: 1) transcription, 2) familiarization with the data, 3) coding, 4) developing a working analytical framework, 5) applying the analytical framework, 6) charting data into the framework matrix, and 7) interpreting the data.[6]

Interview data were analysed according the Framework Analysis methodology using NVivo V.10 (QSR International Pty Ltd, 2012). RB and PB independently applied an inductive approach to the thematic analysis deriving the initial coding.[7] Through a process of discussion involving three authors (PB, RB and SK), further themes were considered until a final coding framework was agreed and applied to the interview data accordingly.

Results

A total of 10 participants, whose baseline characteristics are summarised in Table 1, completed the post-trial interviews. Two interviews were undertaken face to face (Ms. A and Ms. G) and eight by telephone. An overview of themes and subthemes identified from the data is shown in Table 2.

NARRATIVES ABOUT MACS PILOT TRIAL PARTICIPATION AND HOSPITAL CARE

Hospital is a safe place

All participants except Ms. C (who commented only on her favourable impression of the staff rather than the trial itself) specifically described their experience of trial participation as positive overall. Participants seemed generally accepting of the need for hospital admission to further investigate their condition, feeling it was for their own good and that the hospital is a place of safety, despite the view that being admitted to hospital for investigations is time consuming with a lot of waiting time, which they tended to rate unfavourably.

Convenience of care guided by the MACS rule

Interestingly, participants gave a general sense that being treated according to the MACS rule and having their blood samples tested for an additional biomarker had little significance for their care, other than potentially allowing them to be "fast tracked" and go home earlier. Participants expressed trust in the clinicians that the results and recommendations would be accurate. For example, referring to whether she felt anxious about potentially being discharged early, Ms. A said, "Well, if there was a basis for [being anxious] I would have [said it]", apparently highlighting her trust and at the same time her perception of having a final say. Nine of the ten participants favoured the opportunity to be discharged early following the results of their initial blood test. They perceived that

this would reduce the time they spent waiting for results, feeling out of control and taking a passive role.

Mr. J, who was discharged early based on the MACS rule, said, “I thought it was really good. I was far less anxious at home knowing that I had been seen and got the reassurances that I had been given. A good topping and tailing inside and out and of course I was feeling very much better”. Ms. G, who was also discharged early, said, “It was really good, because I was quite tired by then and worn out and you just want to sit in your own house have a bit of sympathy, and I was able to go home and have a shower”. Most of those who did not get the opportunity to go home early also perceived that this opportunity would have been beneficial. For example, Mr. F noted that this would have helped to reassure his family, saying, “If I’d have got home earlier, then my family would have known that I was OK so that would have been a lot better”. However, in contrast, Ms. C was more sceptical about research and felt “pleased to stay in hospital” as she would have felt nervous about an early discharge. She seemed to feel that staying in hospital overnight provided the reassurance she needed to confidently go home.

Participants welcomed the opportunity to return for further tests as a ‘safety net’ in the trial. The two who had been discharged early perceived that the returning for a further blood test was equivalent to a very early follow up, which they welcomed and did not see as an inconvenience. The other participants were asked hypothetically about needing to come back for a blood test and showed in their responses that the time required to return in order to get the extra blood test done at a later date was outweighed by the benefit of being home early. A certain degree of convenience in pre-arranging reception processes and ideally providing patients the possibility to get the blood test done locally to reduce time required were mentioned as important aspects to make it as convenient as possible, highlighted by Ms. G stating “Actually he really made it very smooth. They did

a little note that I could bring with me in the evening and he had arranged for the A&E reception to have my details so that when I turned up I could literally just go in, have the blood test taken and go home so to make that quite easy.”.

Preferences for engagement in care decisions

Within this sample, participants demonstrated a wide spectrum of preferences for their level of involvement in decisions about their own healthcare and participation in clinical research. At one extreme, participants expressed a clear preference for taking a passive role. Mr. F, for example, said, “So, whenever medical people ask me I’ll try to go along with, you know what I mean”. However, others (four participants in total) expressed dissatisfaction with their passive role as a patient in the healthcare system, for example, remarking that they did not feel informed and updated while waiting for serial troponin testing. This left them feeling out of control with no indication on a definitive time frame to guide their wait. Ms. G, who was discharged early through use of the MACS rule, was later re-attended hospital and admitted for investigation. She expressed a strong preference for her initial experience when she was offered early discharge. She said that the invitation to participate in a study gave her some feeling of control over her healthcare, which she desired. She said that participation in the trial was, “partly a distraction and something I could look and decide on”. Therefore for some, even the process of being part of the trial seemed to be beneficial.

Research is ‘extra care’

All interviewees showed willingness to talk about various aspects of clinical care, which were mostly unrelated to trial participation. All mentioned various frustrating experiences with health services, including Ms. C describing a follow up outpatient appointment as “impersonal and a waste of time” and others commenting on administrative issues involving discharge letters not being sent timely or

previous medical information not being available. This seems to demonstrate that they feel frustrated with current health service provision. Interviewees did express that participation in the trial provided the benefit of getting some "extra care" including attention and better follow up due to participating in the trial. None of the participants reported any unexpected adverse events as a result of taking part in the study.

FACILITATORS AND BARRIERS TO PARTICIPATION IN THE TRIAL

Time to settle down

Participants agreed that, once given time to settle down in the ED, they were provided with sufficient and clearly presented information and given the opportunity to ask for clarification about what participation in the MACS trial involved. They welcomed being approached to take part in the trial and reported being able to take an informed decision about participation eventually. They valued good interpersonal skills of the research staff, using words such as "friendliness", "considerateness" and "competence" to describe the behaviour of research personnel who approached them. This seemed to generate trust and to promote participation. For instance, Ms. G described being taken into the "scary red Resus [Resuscitation Room]" when she first arrived, but despite this, feeling positive about participation from the outset, saying, "It was good because [the doctor] waited until I calmed down and settled in the space, which I thought was really good".

It helps others

The participants were also motivated by a sense that the research was worthwhile. Ms. A, for example, decided to take part immediately, "partly because I was a scientist and partly because I think it is interesting, it's the sort of thing that appeals to me". Explaining his motivation to participate despite being generally sceptical of clinical research, Mr. J said, "I am very wary of these things because of this sort of people getting a hold of information about you and you being mithered

to death so I don't sign my name or tick the box usually I don't do it at all, but I felt that it was leading on to something".

Participation seemed motivated by altruism and the expectation that their participation may benefit both them and their families. Ms. G noted, "If people don't take part in these things then nothing moves forward". Similarly, Ms. E said, "It's the only way to get things improved". Ms. B remarked that participation "makes you feel useful" and said, "It gives satisfaction to take part in a trial".

It helps me

However, altruism was not the sole motivation for participants, who also perceived that the research may bring direct personal benefits. For example, Ms. G said, "If I was picked as one of the random people that could do that then I would be able to go home a bit earlier and may just have to come back later on in the evening for a second blood test, so I thought yes, no brainer, yes please". Indeed, participants seemed to value both altruism and the potential to benefit personally. For example, Mr. B said of his participation, "I didn't mind as long as it helps me and anybody". There also seemed to be a feeling that, by participating and potentially going home earlier, the interviewees might help to reduce both their own anxiety and that of family members. Mr. J said, for example, "I have got a wife and only one of our children lives in Manchester. But they are all down and the grandchildren are all, you know. It causes anxiety. Not just to yourself… When you see the anxiety in you and yours it adds to your anxiety".

Positive experience of research

Nine participants said they would have recommended participation in the research to others, although Ms. C did not directly state an opinion. No participants expressed regret about their

participation and they said they felt happy to consider future participation in a related clinical trial. Their positive experience was sufficient to recommend participation in clinical research to others.

Not ready to commit

Participants were asked if they could perceive any potential barriers to participation in the trial. When asked, all but one interviewee stated clearly that they could not; but every participant did then go on to describe a number of factors with potential to compromise their willingness to participate. We have noted that participants often reported the value of having 'time to settle down' after arrival before considering participation in the trial. Some did feel that being in pain on arrival, feeling overwhelmed, alone or anxious about the situation meant that they did not feel ready to commit at the time of the very first approach, although that unease appears to have settled soon after arrival. Ms. C reported that a hearing impediment affected her ability to understand the explanations provided about the research.

Those who described being generally pain-free and comfortable at the time of arrival seemed pleased to be approached and were happy to participate from the outset. However, other participants described feeling less welcoming of the initial approach, most often because they were feeling unwell, in pain or anxious. They seemed to describe feeling overwhelmed by what was happening. For example, Mr. B expressed that the approach may have been made too early after his arrival: "At the time when I first read it I didn't feel all that enthusiastic about it, I just wanted to find out what was wrong. Whether that was just a little bit too quick that I had only just got in, but as the day went on and I felt a little bit better I didn't mind". Ms. H seemed to feel overwhelmed by being asked to read the patient information sheet very soon after her arrival, saying, "When I was asked to read I found it terribly difficult, in those circumstances, with your mind all weary with everything that happened so suddenly".

Concerns about being experimented on

Mr B. reported a dissatisfying clinical experience (apparently unrelated to the trial) of Mr. B having a "learner" trying to take his blood with several failed attempts, causing concerns about the overall clinical competence and a feeling that he had been experimented on. However, participants perceived the intervention (use of a decision rule) as more acceptable because it was non-invasive (unlike a drug trial, for example). Some interviewees described being generally sceptical of clinical research and initially felt anxious about participation. For example, Ms. C seemed to associate medical research with high profile news stories about unethical conduct, saying, "I probably wasn't very cooperative. Because you really only think about the Liverpool Pathway,* things like that. You know you get stupid things in your brain". However, even research sceptics had decided to participate, which seems to have been because they perceived the intervention to be relatively non-invasive. Ms. C went on to suggest that this reassured her about participating in this trial, saying, "They weren't putting anything into my body. They were only taking my blood".

Time consuming and privacy issues

Ms. A speculated that some people might perceive research as time consuming. Perhaps as a result of a misunderstanding, Ms. A believed that participation in the research caused her to stay longer in hospital, saying, "I think because they might have done an extra test I think I had to wait longer". Others noted that some people may be concerned about their privacy. For example, Ms. C said, "I think there are probably people in general who would think [of] research and [be] suspicious, … wondering what [they] are going to do with my details".

* Liverpool Care Pathway for the Dying Patient

Discussion

In this study we explored patient attitudes and perceived barriers to participation in a RCT comparing the use of an early rule out strategy for ACS to usual care. Participants generally felt positive about trial participation, indicating good overall patient-perceived acceptability. All but one participant would have recommended trial participation to others and would consider future participation in research themselves.

Despite this general positive feeling, we did identify several areas for improvement with future trial design. We identified that participants who are in pain, anxious or feeling overwhelmed may feel overburdened if approached about trial participation soon after their arrival in the ED. In this pilot study, participants were asked to provide verbal consent before any trial procedures were undertaken. Because of the time critical nature of the intervention, this meant that participants were generally approached while their initial care (including first clinical assessment and the provision of treatment such as analgesia) was ongoing. Based on the unease of participants in this study, it may be preferable to waive verbal consent for initial trial procedures that do not affect the participant (such as the analysis of blood samples drawn during routine care), and waiting until the patient's condition is more settled and they can provide appropriate written informed consent. Indeed, this approach has been taken in an ongoing cohort study by our group.

Even under ideal circumstances comprehension of randomisation and clinical trial as concepts and making sense of those concepts, represent a serious challenge to many patients.[8,9] Therefore, it can be expected that this critical aspect might be even more difficult to address in an emergency setting clinical trial with the associated timing restraints. In the AHEAD study the problem of informed consent as barriers to recruitment in emergency medicine research has been discussed with a likewise conclusion. They furthermore pointed out that the patient viewpoint can be

influenced by the image portrayed of medical research in the media, which we have noted in some comments including one on the Liverpool Care Pathway.[10]

Our findings do suggest that, in order to maximise the chance of success, future work needs to cater for a wide spectrum of perspectives. For example, while most participants in this study valued the opportunity to take an active role in decisions about their healthcare, some preferred to take a more passive role and to follow the advice of doctors. Similarly, although the majority of participants welcomed the opportunity to return home earlier as a result of the new diagnostic technology (the MACS rule), this feeling was not universal. One participant stated a strong preference for remaining in hospital, where she felt safe. This suggests that an avenue for future work may be to explore shared decision making. With this approach, all perspectives may be catered for. Previous research in this field has shown that patients who are given the opportunity to engage in shared decision making have greater knowledge, play a more active role in their own healthcare and more often choose to terminate further investigation and return home.[11]

Recent findings of a qualitative study investigating the patients' viewpoint on participation in a hypothetical clinical trials in an emergency setting has identified largely comparable themes like trust in medical professionals, concerns about personal wellbeing, motivation being driven by altruism, fear for personal autonomy or misunderstanding of the trial concepts.[1] So despite the specific context of the pilot MACS trial, the themes identified seemed more generally applicable than originally anticipated.

STRENGTH AND LIMITATIONS

Qualitative methods have proven potential to guide optimisation of trial processes. O'Cathain et al evaluated the impact of 296 qualitative studies on various clinical trials, concluding that qualitative methods ought to be employed at the feasibility stage, which is in support of our approach.[12] Although our initial emersion and coding were influenced by the topic guide used in the interview process we allowed for the emergence of alternative themes whenever they demonstrated an association with the feasibility of the MACS rule in clinical practice. While the derivation of codes and the thematic framework is sometimes critiqued for being subjective and prone to introducing bias[13,14], we addressed this by having two independent investigators analyse the interview data to account for the effect of the researcher. Complementing and contrasting views generated discussion between the two researchers involved in the analysis with additional reference to a third, independent researcher (SK) to help ensure that our analysis was a valid reflection of the data, which is a strength of this study.

Our sample size was limited by two key factors: (a) the availability of consenting participants to take part in interviews; and (b) the time that elapsed from participation to scheduling the interview. We noted in the interview process that the time lag between participation and the actual interview caused some problems with recalling the events and information provided at the time of the trial in a number of participants warranting some caution interpreting their statements. However at the time of providing informed consent all participants demonstrated sufficient understanding in order to qualify for participation. While comprehension of the concept might have been sufficient to provide consent participants might still have struggled to make sense of their identity in the trial along the patient to research volunteer continuum, described by Heaven *et al*, and the necessity for a randomised trial.[15]

An unavoidable limitation of this work is that we could only include patients who participated in the trial and consented to be interviewed. We could not explore the perceptions of those who did not take part in the trial. For many reasons this is a poorly studied area.[16] However, based on the variety of different positions participants reported we are confident that the overall transferability within the scope of testing the feasibility of the MACS rules is not heavily affected by the sample size.

Furthermore, we noticed that the lack of interviewing experience for qualitative research by both interviewers might have contributed to patients demonstrating the tendency to provide off-topic answers not related to question asked. While this might be a limitation to the overall quality of our interview data, it also gave patients the opportunity to speak freely about whatever they considered relevant. This has likely strengthened the validity of the more general viewpoint of patients on participating in an emergency setting RCT. The effect of the interviewers being mainly independent clinicians is debateable and could potentially have kept some participants to voicing concerns. The fact that a small number of interviews was conducted by the principal investigator of the MACS pilot trial due to practical reasons, could be viewed as a potential conflict of interest and was kept to an absolute minimum.

Another limitation to our sample of interviewed participants is its homogeneity in terms of age distribution and ethnic diversity, though considering the original MACS trial population, our sampling appears to be reasonably representative. Nevertheless, some caution might be warranted in extrapolating our findings to other patient groups in the MACS trial not represented in the interviews.

Conclusion

Patients with suspected ACS felt positively about their participation in a pilot RCT comparing the use of the MACS rule to standard care. They welcomed opportunities to play an active role in their care, to reduce unnecessary waiting and to have the opportunity for follow up blood tests as a 'safety net'. We also identified several potential limitations to the trial design, which should be considered in the design of future larger trials. Themes identified in this specific context demonstrated great similarity with known barriers to patient recruitment, especially in the emergency medicine research setting.

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Tables

Table 1: Baseline characteristics and identifiers of interview participants

Participant Identifier	Age	Gender	Ethnicity	Allocated group at trial participation	Hospital disposition
A	80	Female	White British	Intervention group	Admission
B	80	Male	White British	Intervention group	Admission
C	76	Female	White Irish	Intervention group	Admission
D	54	Female	White British	Control group	Admission
E	84	Female	White British	Control group	Admission
F	74	Male	White British	Control group	Admission
G	36	Female	White British	Intervention group	Early discharge
H	69	Female	White British	Control group	Admission
I	77	Female	White British	Control group	Admission
J	71	Male	White British	Intervention group	Early discharge

Table 2: Summary of identified themes

Theme	Subthemes
Narratives about MACS pilot trial participation and hospital care	Patients welcomed the convenience of care guided by the MACS rule Participants welcomed the opportunity to return for further tests as a 'safety net' Patients' preferences about their role in healthcare decisions varied widely Research is 'extra care' Additional narratives
Facilitators and barriers to participation in the trial	Participants welcomed being approached to take part in the trial once they had time to settle down People were motivated to participate both by altruism and the perception that the research may benefit them and their families Participants felt positively about trial participation and would recommend it to others

	Some participants could not agree to participate until they felt ready Concerns about being experimented on Perceiving research as time consuming