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Women’s views about management and cause of urinary tract infection: qualitative interview study

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ABSTRACT

Objectives To explore the views of women with urinary tract infection on the acceptability of different strategies for managing the infection, including delayed use of antibiotics, and the cause of infection.

Design Qualitative interview study with semistructured one to one interviews within a randomised controlled trial of different management strategies. Analysis drew on some of the principles of constant comparison to generate key themes grounded in reported experiences and understandings.

Setting Seven general practices across four counties in southern England.

Participants 21 women presenting to general practices who were taking part in the larger trial.

Results Women preferred not to take antibiotics and were open to alternative management approaches. With a strategy of “antibiotic delay” some women felt a lack of validation or that they were not listened to by their general practitioner. Women attributed urinary tract infection to lifestyle habits and behaviours, such as poor hygiene, general “negligence,” and even a “penalty of growing old.”

Conclusion A clear acknowledgment of women’s triggers to consult is needed. If women are asked to delay taking antibiotics, the clinician must address the particular worries that women might have and explain the rationale for not using antibiotics immediately.

INTRODUCTION

Acute urinary tract infection is one of the commonest acute bacterial infections among women. Most women presenting in primary care are prescribed an antibiotic. Conventional courses of antibiotics probably help to resolve symptoms but are also likely to have side effects, including skin rash, vaginal symptoms, and other side effects. The strategy of universal use of antibiotics in these women is being questioned in part because the condition is often self limiting and non-pharmacological alternatives—such as the use of cranberry juice, teas, or herbal remedies and potassium citrate or sodium bicarbonate—exist, although the evidence for effectiveness is weak. The potential effectiveness of antibiotics must also be balanced against wider issues for the National Health Service (NHS), particularly the mounting concerns about increasing workload for self limiting illness and the growing problem of antibiotic resistance. The use of diagnostic techniques and antibiotics might encourage belief in antibiotics and in the necessity of seeing a general practitioner for the problem, thus “medicalising” a condition that is often self limiting. This leads to greater antibiotic use and increased antibiotic resistance.

Given these concerns and the limited evidence base for alternative management options, there was a need for trials to allow estimation of the advantages and disadvantages of antibiotics, antibiotic strategies, and non-antibiotic alternatives. We conducted a pragmatic randomised controlled trial to test several management strategies, including antibiotic delay. Qualitative interviews nested in the trial explored interviewees’ attitudes towards antibiotics, their experience of a delayed antibiotic prescription, and their views on the cause of urinary tract infection.

METHODS

Participants and procedure

Participants were recruited from a large randomised trial of different management strategies, in which patients were randomised within the consultation to one of five management groups: empirical antibiotic treatment; empirical delayed antibiotics; antibiotic targeted by symptom score (two or more of urine cloudy, urine with offensive smell, moderately severe dysuria, or nocturia); antibiotic according to dipstick algorithm (nitrates or leucocytes and a trace of blood); or mid-stream urine analysis with symptomatic treatment until culture and sensitivity results were available and then antibiotics targeted according to culture results.

To be eligible for inclusion participants had to be taking part in the larger trial, have consented to have a single face to face interview, and have been allocated to a management group in which delayed antibiotics were specified by the protocol, meaning this option was discussed and negotiated flexibly with each patient, and they were given access to the delayed prescription at any stage. The third criterion ensured that we were able to explore participants’ thoughts on the appropriate treatment of urinary tract infection and their views on the acceptability or otherwise of being
Patients were offered symptomatic treatment until the results of the test were known. This initially. Patients not fulfilling this criterion (which we estimate had a sensitivity of 71%) were allergic to trimethoprim they were offered an alternative (cefaclor or cefalexin) as this was not a trial of antibiotics per se but a trial of management/advice strategies.

Empirical delayed antibiotics

All patients were advised to drink plenty and offered a delayed antibiotic prescription to be used if symptoms did not start to improve after 48 hours (doctors were asked to leave a prescription at the front desk for patients to collect as necessary, or they could negotiate with the patient if they wanted to take the prescription away). The rationale is that 40% of patients with suspected urinary tract infection do not have infection, and, even in those with laboratory diagnosed infections, the illness is likely to be self limiting.

Symptom score

Patients who had two or more of the following features were offered antibiotics immediately (which we estimate had a sensitivity of 71%): a smell on examination, patient’s report of moderately severe dysuria, or patient’s report of moderately severe nocturia or patient’s report of two or more features were also offered a delayed antibiotic prescription to use if their symptoms were not settling after a few days.

Dipstick

Patients who had either nitrites or leucocytes and a trace of blood were offered antibiotics initially. Patients not fulfilling this criterion (which we estimate had a sensitivity of 71%) were offered a delayed antibiotic prescription to use if their symptoms were not settling after a few days.

Midstream urine analysis

This was the only group in which a midstream urine sample was routinely collected. Patients were offered symptomatic treatment until the results of the test were known. This is the “reference” method of diagnosing infection and of targeting antibiotic use.

RESULTS

Participants

Thirty three women were approached to take part in the interview study. Twenty seven agreed and 21 (aged 21-64, median 40) were interviewed before data saturation was reached (one tape failure meant that 20 interviews were available for analysis). Reasons for refusal included being too busy or unavailable in working hours. Refusals for both the trial and then for the qualitative study were low. The characteristics of women participating in the qualitative study were similar to the overall trial cohort: married 65% v 73%, past cystitis 88% v 85%, number of medical concurrent problems 3.0 v 2.6, age leaving education 17.6 v 17.6, severity of frequency of urinary symptoms at baseline 3.5 v 3.5, respectively.

Patients’ experiences

In their interviews patients traced their experiences from the onset of symptoms and their attempts to self manage, through to their final decision to attend a general practitioner. Many described their initial reluctance to attend their general practitioner. In most cases the severity or duration of symptoms, or both, eventually prompted a visit (tables 1 and 2).

Patients’ views about the management of urinary tract infection

Of the 20 interviews recorded, 13 women were asked to delay taking antibiotics and of these 10 viewed the strategy positively (patients 2, 3, 5, 6, 7, 9, 12, 14, 15, 20) and three (patients 8, 11, 17) reported negative experiences. The preponderance of positive reports about the experience of delayed medication or having
non-drug alternatives, or both, corresponded with participants’ reported reticence about relying on antibiotics. Two interviewees expressed a preference for antibiotic medication. One indicated that fear of worsening symptoms had prompted her to seek help in a preventative fashion and for her the optimal treatment was antibiotic medication (patient 7). The other’s preference was based on her experience of successful treatment in the past.

Seven interviewees reported being prescribed antibiotic medication immediately (patients 1, 4, 10, 13, 16, 18, 19) (table 3).

**Positive experiences**

**Being offered an alternative to antibiotics**

Three of the interviewees reflected on their allocation to the “delay” arm of the trial in highly positive terms.

“She [the nurse] said . . . if you agree to take part then you’ll have an envelope and you may be given antibiotics, you may not . . . and I said well I really would rather not have antibiotics . . . but luckily enough . . . I got the cranberry juice [laughter] one . . .” (patient 5)

“I went in and I didn’t want to take antibiotics so I was quite glad when he gave me this other [Uvacin, a herbal over the counter remedy]” (patient 12)

**Avoiding side effects of antibiotics**

Participants spoke about their initial reactions to antibiotic delay in terms that suggested a careful weighing of the consequences of immediate use versus delayed or no use.

“Well, I sort of sat there and went, oh, not three more days, but then when I thought about the side effects, it was like, well . . . do I really want the side effect [of thrush] . . . then that’s going to be another three, four days . . . of more pain in the same area and I just thought, well . . . you’ve had it for seven days and if you wait another three it will hopefully have gone anyway” (patient 14)

Most of the participants with experience of antibiotic use had developed thrush (one of the commonest side effects) as a consequence and this mediated their desire for antibiotic medication.

“I know that thrush can be a side effect of the antibiotic and I have suffered that in the past as well, so anything to avoid that situation” (patient 6)

Avoiding side effects was a strong driver for viewing antibiotic delay positively, as was a reported belief in and preference for “natural” alternatives.

“Antibiotics in general have caused me a quite severe rash on my legs . . . I suppose that is one of the reasons but I don’t think that’s the prime reason. I think the main reason is that I just don’t think it is right for the body to keep taking them” (patient 5)

**Having a general practitioner who provides “natural” alternatives**

Being offered an alternative to antibiotics was particularly well received by patients who indicated a belief in holistic medicine and wherever possible the avoidance of orthodox medicine.

“I really like the fact that my GP, who I mentally associate with you know antibiotics and drugs of some sort, has suggested a herbal remedy and fruit juice . . . I think it’s great . . . rather than trying to give me antibiotics straight away . . . I’d love a practice that really combines all the kind of natural therapies . . . whether it be herbal, homoeopathic, or through nutrition and diet” (patient 2)

“He didn’t give me antibiotics, but I wouldn’t have taken them anyway . . . I’m not a great believer in antibiotics” (patient 15)

Despite being in pain, one woman’s desire to avoid orthodox medication meant that delay was still viewed
Reasons given by participants for the ‘no delay’ decision in women with suspected urinary tract infection

<table>
<thead>
<tr>
<th>Patient</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Interstitial cystitis (chronic inflammation of bladder wall)</td>
</tr>
<tr>
<td>10</td>
<td>He didn’t suggest waiting because “I was in such a state”</td>
</tr>
<tr>
<td>13</td>
<td>She told the doctor what she wanted and did not delay or try Uvacin</td>
</tr>
<tr>
<td>16</td>
<td>No delay recommended, “she felt in this case, because I’d already . . . tried other courses of action and that was seven days and the symptoms were becoming more severe rather than better, that antibiotics was probably the right course of action to take”</td>
</tr>
<tr>
<td>18</td>
<td>Tried antibiotic and it did not work, then had to try another type</td>
</tr>
<tr>
<td>19</td>
<td>Given antibiotic immediately for immediate use</td>
</tr>
</tbody>
</table>

Table 3

as appropriate. Her positive disposition was no doubt reinforced by her recovery without intervention.

“I was in quite a lot of pain, I thought, well, OK, I can wait, I’ll give it, you know, I’ll give it four or five days and then see if I get any better, and, and I did get better” (patient 9).

Having a “back-up” prescription and feeling validated

Just one participant explicitly mentioned that the recommended delay was acceptable because of her “faith” in her general practitioner, “I have a great deal of faith in my GP . . . and because he was happy to suggest the Uvacin, I was happy to accept that” (patient 6).

Others who were offered a delayed antibiotic reported that they derived comfort from the knowledge that a prescription was available if required.

“I guess in the back of my mind there was a slight reassurance that if all else fails I’ve got it [the prescription]” (patient 6).

“I felt OK because I knew that the prescription was there if I needed it” (patient 20).

Negative experiences

Not feeling validated

Receiving a (delayed) antibiotic prescription contributed to participants’ feelings that their symptoms had been validated and taken seriously. By contrast, the three participants who reported negative experiences of the delay strategy spoke of their concern that their knowledge had been ignored.

“I’m quite willing to listen, but I know my own body” (patient 8).

It was clear that the patients who reported negative experiences doubted whether their general practitioners had acknowledged their symptoms or accepted the legitimacy of their complaint.

“He really didn’t want me to have [an antibiotic] he was a bit blasé about it and um . . . I thought I told him . . . I was sort of passing blood” (patient 11).

Feeling that their complaint was not viewed as legitimate by their general practitioner could be influenced by participants’ knowledge that antibiotics had the potential to alleviate symptoms more rapidly compared with no antibiotic.

“[I could have] got rid of it a lot sooner and gone back to work, instead of missing time at work” (patient 11).

Too late to wait

For a few participants, delay had proved to be alarming because their symptoms had, in their opinion, “just gone past the waiting stage” (patient 8). Indeed, this particular participant did not delay, as recommended, because her symptoms were interfering with her work. She reported that she was in “terrible pain and it was frightening” and “I was nearly in tears.” The seven participants in the delay arm of the trial who were offered immediate antibiotics had described their symptoms in similarly serious terms. Understanding women’s experiences like these helped to explain why some participants did not feel validated or taken seriously—that is, a consultation that resulted in no antibiotic or a delayed antibiotic could symbolise a rejection of their symptoms.

Another interviewee who expressed dissatisfaction spoke about how she had already attempted self help measures and in this way had already delayed.

“I think probably at the time I just thought well I’ve waited this long, I’ve done all the help, self help measures myself, um . . . the fact that he was asking [slight laughter] me to delay even longer was, oh, I don’t want to do this but I think I did and then I think it got to the stage where I just thought no” (patient 17).

Thus, a general practitioner’s recommendation to delay could carry the risk of invalidating the basis for a patient’s consultation and the attempts they had made to self care before their attendance. Importantly, when faced with continuing symptoms women reported that they would prioritise knowledge of their “own bodies” and exercise their right to collect and use the “delayed” antibiotics or attend their general practitioner again.

Causes of urinary tract infection

All participants were asked what they thought caused urinary tract infection. Table 4 shows the range of causes volunteered by participants. Fifteen of the 20 women interviewed discussed previous experiences of urinary tract infection or cystitis, yet when asked to discuss the natural history/signs and symptoms of urinary tract infection most of the women struggled. Responses also indicated a need for increased opportunities for patients who attend with a suspected urinary tract infection to discuss the condition and the evidence (and uncertainty) about the effectiveness of antibiotic medication.

Lifestyle explanations were often cited as contributing to urinary tract infection. Women mentioned refraining from certain behaviours such as “drinking caffeine,” “not drinking too much wine,” and not being “negligent” when it comes to cleanliness. Embedded in most participants’ reports was a “duty to stay healthy” and to live a life centred on the concept of self discipline (good diet, exercise, washing after sex,
Table 4 Causes of urinary tract infection according to women presenting to primary care.

<table>
<thead>
<tr>
<th>Patient</th>
<th>What do you think causes a urinary tract infection?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Wiping the wrong way, low immunity, and antibiotics</td>
</tr>
<tr>
<td>2</td>
<td>Once you have had it, tend to be more susceptible, sex, diet, and lifestyle. Wine and drinking Bovril caused &quot;mine&quot;</td>
</tr>
<tr>
<td>3</td>
<td>Age, &quot;drying up,&quot; &quot;penalty of growing older.&quot; Long bicycle ride on holiday and sitting on damp towel</td>
</tr>
<tr>
<td>4</td>
<td>Deviant case; interstitial cystitis</td>
</tr>
<tr>
<td>5</td>
<td>Dehydration, infection after diarrhoea, age, &quot;have to be more careful as get older,&quot; stress</td>
</tr>
<tr>
<td>6</td>
<td>Dehydration, alcohol, enhanced sexual activity, being on holiday</td>
</tr>
<tr>
<td>7</td>
<td>&quot;Don't know really&quot;, drugs and antibiotics? People go through &quot;phases&quot;</td>
</tr>
<tr>
<td>8</td>
<td>Dehydration, sex, perfumed products, &quot;that's all I know&quot;</td>
</tr>
<tr>
<td>9</td>
<td>&quot;I'm not sure really,&quot; &quot;I think some of it is cleanliness...&quot; &quot;I sit for [prolonged periods] and toilet breaks are very quick...&quot; You leave it until you have to go&quot;</td>
</tr>
<tr>
<td>10</td>
<td>I'm a bit perplexed about it 'cause it's something that I never had... growing up... I've heard that it's associated with the menopause. 'I assume it can be caused by your sex life... or some irritation. I've been told that it's... a germ and it can be caused by a germ in the water.&quot; Individual cause: &quot;doesn't seem to be any one particular cause&quot;</td>
</tr>
<tr>
<td>11</td>
<td>A bug? Wiping the wrong way, tight clothes, &quot;or am I just making that up.&quot; Individual: &quot;I don't know in my case what [causes it], because I don't think I've been doing anything different... to suddenly get it at my age [mid 50s] and not ever had it before... I don't know&quot;</td>
</tr>
<tr>
<td>12</td>
<td>I've read loads on it; I should know [laughter from both]. I've had all the books out. Everytime something goes wrong I read all the books... I don't know... It's... I don't know, I can't think of it now&quot;</td>
</tr>
<tr>
<td>13</td>
<td>Active sex life</td>
</tr>
<tr>
<td>14</td>
<td>I don't know... sometimes if I've... become sexually active, I always get cystitis... 100% I can guarantee it. Hence I just don't bother anymore [laughter]. No, go away, because I know I'm going to get... it tends to be around my period that I get it... It's yeah, if I'm, if I'm, if I'm in a relationship, it's a, it's a definite [laughter]... It's kind of inconvenient, but you know&quot;</td>
</tr>
<tr>
<td>15</td>
<td>Individual cause: &quot;I feel that it is actually just a bit of, well, a bit of bad luck and perhaps a little bit of lack of concentration when going to the loo, because I do remember... being a little less careful than I should normally have been&quot;; negligence; &quot;the more stressed you are the more it... makes your body vulnerable. I think it lowers your body's resistance in so many ways&quot;</td>
</tr>
<tr>
<td>16</td>
<td>&quot;People don't drink enough... I think in this case, that is maybe what led to mine... and not going to toilet when you need to, you hold on a lot. I think perhaps those two things do contribute to it a great deal!&quot;</td>
</tr>
<tr>
<td>17</td>
<td>Pregnancy, hormones, menstruation, tampons (irritation not infection), sex (aggravation)</td>
</tr>
<tr>
<td>18</td>
<td>The doctor told me it was to do with sexual activity, so I presume that's what it was because things had changed in my life which I explained to her&quot;</td>
</tr>
<tr>
<td>19</td>
<td>A highly moral discourse again; &quot;I will be prepared to admit it's my own fault [laughter] 'cause I'm terrible, I just, coffee addict and... I just hardly ever drink water... I'm trying... to do better&quot; I did have a really hot temperature... I didn't know whether I was having hot flushes... I'm 44 [slight laughter] I thought, oh, maybe I might be having the change&quot;</td>
</tr>
<tr>
<td>20</td>
<td>&quot;Not drinking enough&quot;</td>
</tr>
</tbody>
</table>

*Seven women were in symptoms score group, nine in empirical delayed group, and two each in symptoms score and mid-stream urine groups. We selected women for interview who had been asked to delay taking antibiotics to obtain their views on delay strategy. This would not apply to women in immediate empirical antibiotic group.

DISCUSSION

From this qualitative interview study we found that women with urinary tract infection want to avoid taking antibiotics and are open to alternative management strategies, including a delayed antibiotic prescription. They valued the opportunity to avoid the unwanted side effects associated with antibiotics and to allow "natural" healing of the body. For most, delayed prescribing was reassuring on two levels. Firstly, having a prescription waiting in the general practice reception was reassuring because it meant that they could collect the antibiotic should their symptoms worsen. Secondly, having a prescription available to them validated patients' experiences of their symptoms. There were a few negative experiences of delay, when being asked to "wait some more" served to undermine the legitimacy of their visit. Finally, our study indicates that women with and without previous experiences of urinary tract infection might not fully understand the causes or might draw on a theory of self blame and negligence, or both. Some women seemed to view antibiotics as necessary because they believed that they expedite the alleviation of symptoms.

Results in context

Urinary tract infections are common and are of concern to generalists (general practitioners, family doctors, urgent care) and specialists (including gynaecologists, urologists, and renal physicians). Little is available, however, on women's experiences and views of urinary tract infection and its management, especially the particular issue of alternative management strategies.

The strategy of antibiotic delay can be used in the management of sore throat and conjunctivitis and has been found to be acceptable to patients. The study of Everitt et al also indicated that patients will accept and encourage an alternative management strategy, including antibiotic delay. Increased information for and discussion with women attending for urinary tract infection is vital, however, if they are to better understand the rationale that underlies antibiotic delay. A full understanding might help to increase women's sense of validation and of being taken seriously.

Women might attribute urinary tract infection to issues of poor cleanliness and general "negligence." Lifestyles have been fully commercialised, and it is unsurprising to find that participants spoke in terms that suggested a (moral) duty to "consume a healthy lifestyle." It is important for general practitioners to be aware of them in the clinical encounter and be mindful of the consequences of such beliefs. For example, the cause of urinary tract infection might come to be construed as indicative of personal weakness. Women who tend to use a theory of self blame and negligence might be particularly vulnerable to feelings of not being taken seriously when their doctor proposes a strategy of no antibiotic or delayed antibiotic.

Strengths and limitations

Representation of thematic analysis can result in the de-contextualisation of speakers' words from the original sequence, which might misrepresent the intended meaning. We took care to analyse the participants' words in the broader context of the surrounding speech to ensure a fair interpretation of the meaning of the fragments reported here.

Women indicated some discomfort when asked to discuss the cause of urinary tract infection. It is difficult to know whether this reflected "limited knowledge" or whether the context of the interview might have caused
WHAT IS ALREADY KNOWN ON THIS TOPIC

Patients’ understanding of the causes of urinary tract infection and their views on and experiences of different management strategies are not well understood.

The potential effectiveness of antibiotics for urinary tract infection needs to be balanced against wider issues such as side effects, antibiotic resistance, and general practitioners’ workload.

WHAT THIS STUDY ADDS

Women with urinary tract infection want to avoid taking antibiotic medication and are open to alternative management strategies, including a delayed antibiotic prescription.

Clinicians need to acknowledge women’s experiences before consulting (including attempts to self-care), and if women are asked to delay taking antibiotics, the clinician must address the particular worries that women might have, and explain the rationale for not using antibiotics immediately.

or exacerbated this discomfort. The questions might have been viewed as a “test” in which participants could be right or wrong. Indeed, answers were often prefaced or closed with the phrase “I don’t know” or some similar epistemic downgrade. Regardless of these features, interviews suggest a need for improved information about urinary tract infection and greater dialogue between doctors and patients, even when patients have previous experience of the condition.

Regarding sample selection, only a few women declined to take part in the trial or the interviews. Allocation to groups was random, and so selecting from one group (that is, delayed antibiotics) should not bias the type of patient selected for interview but did allow us to focus the qualitative work. The randomised controlled trial of different management strategies for urinary tract infection provided an ideal opportunity to explore patients’ views and experiences of different management strategies. These views do not represent anticipated or hypothetical experiences but rather views based on women’s experiences of the actual management strategy proposed, which is important for the care of patients. The women interviewed, having already consented to take part in a trial, might have been more receptive to the concept of delayed treatment. The information about alternative management strategies, however, was presented in a balanced, neutral way (all general practitioners were in equipoise on the aims of the study and how to recruit patients and obtain consent). We are confident that the views expressed by the women relate to their experiences of the particular management strategy they were assigned to. Moreover, our thematic findings resonate strongly with other relevant studies, and this increases the face validity and transferability of our findings.

As with all interview studies the kind of data generated is a limitation. Interviews provide useful perspectives on events or experiences but not a window to events as they occur. Qualitative interviews were the optimal method of data collection for this relatively unexplored and personal condition, offering insight into patients’ experience and views. Future work could usefully explore the negotiation of delayed antibiotic prescribing and other options in situ.

Implications for future research or clinical practice

Patients’ expectations do not necessarily revolve around healthcare professionals’ prescription note-pads. Rather, expectations are likely to centre on being understood and believed and in being helped to understand the rationale for alternative management strategies, such as antibiotic delay.

Some healthcare professionals might overestimate patients’ demand for antibiotics. And patients might also overestimate the desire of healthcare professionals to prescribe.

“We know that viral infections don’t necessarily respond to antibiotics but I do think that there is a general feeling out there that a lot of GPs will just go yeah here’s a course of antibiotics just to get you out of the door and move on to the next one” (patient 2)

Background expectations like these have potential to influence the consultation. If doctors recommend delayed antibiotics, the reasons must be clear. Equally, doctors need to be cautious in assuming that patients expect antibiotics. In our study, it seemed that the option to avoid the side effects of antibiotic treatment could lead to a sense of relief, and the opportunity to try other approaches was viewed positively. The next challenge is to establish whether and how these findings relate to clinical practice outside the context of a trial. A priority for exploration is whether there are advantages to offering an alternative to antibiotics when no antibiotic or a delayed antibiotic is recommended.

Overall, findings suggest that the particular strategy of delay could represent a happy medium for patients whereby they feel validated and reassured by the availability of a prescription, “just in case.” A clear acknowledgement of a woman’s triggers to consult is needed. If women are asked to delay taking antibiotics, the clinician must address the particular worries that women might have and explain the rationale for not prescribing antibiotics immediately.

We thank the practices that took part in the study and the patients who gave their time and shared their experiences and thoughts. The UTIS team comprises (in alphabetical order) C Hawke, J Lowes, K Martinson, MV Moore, MA Mullin, D Turner, and G Warner. Contributors PL had the original idea for the overall protocol and led the funding application. GML had the idea for the qualitative component of the study. All authors contributed to the development of the protocol and overall supervision of the study. ST, the trial coordinator, conducted the interviews with GML. GML and PL led the qualitative analysis and drafted the paper. All authors contributed to the writing of the final version of the paper. GML is guarantor.

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Data sharing: No additional data available.