



## ■ FOOT &amp; ANKLE

# Barriers to recruitment to an orthopaedic randomized controlled trial comparing two surgical procedures for ankle arthritis

A QUALITATIVE STUDY

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## Aims

A multicentre, randomized, clinician-led, pragmatic, parallel-group orthopaedic trial of two surgical procedures was set up to obtain high-quality evidence of effectiveness. However, the trial faced recruitment challenges and struggled to maintain recruitment rates over 30%, although this is not unusual for surgical trials. We conducted a qualitative study with the aim of gathering information about recruitment practices to identify barriers to patient consent and participation to an orthopaedic trial.

## Methods

We collected 11 audio recordings of recruitment appointments and interviews of research team members (principal investigators and research nurses) from five hospitals involved in recruitment to an orthopaedic trial. We analyzed the qualitative data sets thematically with the aim of identifying aspects of informed consent and information provision that was either unclear, disrupted, or hindered trial recruitment.

## Results

Recruiters faced four common obstacles when recruiting to a surgical orthopaedic trial: patient preferences for an intervention; a complex recruitment pathway; various logistical issues; and conflicting views on equipoise. Clinicians expressed concerns that the trial may not show significant differences in the treatments, validating their equipoise. However, they experienced role conflicts due to their own preference and perceived patient preference for an intervention arm.

## Conclusion

This study provided initial information about barriers to recruitment to an orthopaedic randomized controlled trial. We shared these findings in an all-site investigators' meeting and encouraged researchers to find solutions to identified barriers; this led to the successful completion of recruitment. Complex trials may benefit for using of a mixed-methods approach to mitigate against recruitment failure, and to improve patient participation and informed consent.

**Cite this article:** *Bone Jt Open* 2021;2-8:631–637.

**Keywords:** Ankle osteoarthritis, Randomized clinical trials, Recruitment, Orthopaedic, Patient experience, Ankle arthrodesis, Ankle fusion, Ankle arthroplasty

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doi: 10.1302/2633-1462.28.BJO-  
2021-0074.R1

*Bone Jt Open* 2021;2-8:631–637.

## Introduction

Clinical researchers often meet significant challenges recruiting patients to randomized controlled trials (RCTs) to evaluate surgical interventions. Any new technology,

procedure or therapy needs evidence and so the purpose of clinical trials is to produce the requisite evidence of clinical or cost effectiveness prior to widespread adoption. In cases where technologies are already being used

widely prior to an RCT, this could jeopardize equipoise.<sup>1,2</sup> Extensive qualitative research has provided a nuanced understanding of the trial recruitment processes from the perspectives of potential participants, clinicians, and trialists, including reasons for treatment preferences and unexpected misinterpretations of information.<sup>3-5</sup> In a study of six RCTs aimed at understanding the recruitment process, Donovan et al<sup>6</sup> found clear obstacles to recruitment. These were readily acknowledged issues that participant sites were able to identify, such as logistical difficulties, fewer eligible patients than initially expected, and patient treatment preferences. They also found underlying challenges related to recruiters' roles that resulted in conflict and produced discomfort. For example, recruiters often experienced conflict between their research and clinical roles. To address these challenges, a complex recruitment intervention, known as Qualitative Research to Improve Recruitment to Trials (QuinteT), has been developed to optimize recruitment processes. The intervention has been applied to over 30 RCTs and uses methods such as interviews with active recruiters and audio recordings of trial information, consultations to understand recruitment issues, and develop targeted recruitment strategies.<sup>7</sup>

We present an exploratory study of recruitment issues using the QuinteT methods in a selection of sites participating in an orthopaedic trial that struggled to achieve its estimated recruitment target. The recruitment period was extended, and approaches determined from the qualitative study contributed to the subsequent successful recruitment to the study.

## Methods

Our approach was theoretically informed by critical realism applied to social science. Critical realism proposes that through scientific enquiry, we can understand enduring features of our reality; however, knowledge is transitory and always situated within a historical, social, and cultural context. Therefore, the aim of any investigation is to create a plausible description or explanatory account of the object of study.<sup>8</sup> Semi-structured telephone interviews were conducted with principal investigators and recruiters at participating centres involved in the orthopaedic RCT. An interview topic guide was used to ensure comparable areas were covered in each interview (see Supplementary Material). Staff interviews were audio recorded and transcribed with consent. Transcripts and notes were analyzed thematically by AR, a qualitative researcher, using techniques of constant comparison and case study approaches until data saturation was reached.<sup>9</sup> The coding was carried out using qualitative data analysis software (NVivo version 12; QSR International, Australia).<sup>10</sup> Detailed descriptive accounts of the themes were produced and discussed with the qualitative research team.

Audio recordings of patient appointments were conducted by recruiting teams at participating centres. Written informed consent to enter the qualitative study was obtained from staff and patients, after explanation of its aims and methods and prior to recording of the RCT recruitment consultation. Site teams were asked to audio record appointments of two patients in which recruiters provided information about the RCT, and asked patients if they would like to become participants.

Audio recordings of appointments were analyzed thematically.<sup>7</sup> Analysis aimed to identify and document aspects of informed consent and information provision that was either unclear, disrupted, or hindered recruitment to the orthopaedic RCT. The coding covered all the themes discussed by participants. AR created the initial coding and JB coded a selection of the interviews and audio recordings independently. DG and AG reviewed and checked the final coding structure. Disagreements were resolved through discussion among team members.

We used a purposive sampling method acquiring our dataset to provide a rapid response to the research question. We targeted research teams at sites that were: 1) actively recruiting to the Total Ankle Replacement Versus Arthrodesis (TARVA) trial (i.e. exclude centres that had not recruited participants); and 2) willing to engage in interviews and audio recordings of recruitment appointments. AR and DG presented the design of the qualitative study of recruitment to RCT investigators at their annual meeting and followed-up with invitations to take part in the qualitative study. Data collection lasted for four months between June and September 2017. The study received ethical approval from London Bloomsbury Research Ethics Committee (14/LO/0807).

**Context of the trial.** The qualitative study of recruitment was conducted during the recruitment period of a multicentre, randomized, clinician-led, pragmatic, parallel-group orthopaedic trial of two surgical procedures. It compared total ankle arthroplasty with arthrodesis (fusion) surgery in patients aged 50 to 85 years with end-stage ankle arthritis. The recruitment target was 328 patients over 24 months at 12 centres. Patient-facing trial literature had been carefully reviewed for equipoise. Unfortunately, the recruitment target was not achieved on time, with the recruitment rate below assumptions, requiring additional trial sites and a funded extension to recruitment. The qualitative study of recruitment was conducted at the beginning of the extension period between June and November 2017 and presented its findings at an investigators' meeting in November 2017. The trial finally completed its recruitment in January 2019, with initial reporting due in 2022.

## Results

Five RCT site teams agreed to take part in the qualitative study of recruitment. We conducted 11 staff interviews

**Table 1.** Staff interviews and audio recordings of recruitment consultations per site.

Site	Staff interviews	Patient recordings submitted	
Type	Role in trial	Description	Decision
Site A: specialist orthopaedic hospital	Principal investigator Research associate	PI and female patient	Open to participate
		PI and male patient	Steroid injection
		RA and male patient	Open to participate
Site B: teaching hospital	Principal investigator Research associate	PI and male patient	Steroid injection
		PI and male patient	Time to think
Site C: teaching hospital	Trial administrator	No recordings submitted	
Site D: teaching hospital	Principal investigator Research associate Research coordinator	PI and RA with female patient	Willing to hear about trial
		PI and RA with male patient	Willing to hear about trial
		RA and male patient	Open to participate
Site E: specialist orthopaedic hospital	Principal investigator Research associate Research coordinator	RA and male patient	Open to participate

PI, principal investigator; RA, research associate.

that lasted 20 minutes, on average, and analyzed audio recording of recruiting consultations with nine individual patients. Orthopaedic surgeons had the role of principal investigators (PIs), and research nurses and research physiotherapists had the role of research associates (RAs) in this trial. Details of the data collected from each site are shown in Table 1.

**Recruiters' views on patient preferences for the intervention arm.** Interviewees considered the main obstacle to recruitment to the RCT was that patients had a strong preference for one treatment (ankle arthroplasty) over the other (ankle arthrodesis). Recruiters did not recall any patient who preferred arthrodesis, which is contrary to the study findings. They felt that only patients who did not have a strong preference were amenable to participation in the study. Interviewees reported the following patient reasons for preferring ankle arthroplasty:

- Concerns about fusion restricting range of motion.
- Assuming ankle arthroplasty should be as successful as hip and knee arthroplasties.
- Surgeon was a well-known expert on ankle arthroplasty.
- Internet/family and friends' recommendations.
- Referred for arthroplasty because local surgeon only performs arthrodesis.

Furthermore, RAs expressed views that matched patient reasons for preferring ankle arthroplasty. One RA said: "after arthroplasty patients may have the option of fusion; yet after fusion they do not have an alternative". Another RA explained, "you can't get away from the fact one minute you have a joint that moves and the next minute you don't". One RA noted, "if you asked anybody 'would you prefer a joint fused or replaced?' I think most of them would say replaced". These views contributed to the perception of this trial as a "hard sell" to patients, an obstacle commonly found in other trials that could be overcome with targeted recruitment training.<sup>11</sup>

**A complex patient pathway from eligibility to randomization.** Recruiting teams encountered difficulties identifying eligible patients and inviting them to take part in the RCT on regular basis. One RA said, "patients may come all at once or not at all for months". These patients had suffered with ankle arthritis for many years but only became eligible for the RCT after a diagnosis of end-of-stage ankle arthritis. Some patients needed to postpone their ankle surgery in order to have treatment for other musculoskeletal or general comorbidities.

**Logistics of recruitment.** Recruiters mentioned logistical issues that made recruitment to this RCT difficult, such as lack of space in clinics to conduct research, clinic cancellations, and poor communication between clinical and research teams on potential participants. These issues became exacerbated as trial recruitment continued to underperform against the recruitment targets. These are common issues for large multicentre trials and have been widely reported. However, their prevalence has been shown to be indicative of hidden challenges such as lack of equipoise.<sup>6</sup>

**Conflicting individual recruiter views on equipoise.** According to the chief investigator (AG), orthopaedic surgeons agreed that finding a high level of evidence for the best management of ankle arthritis was a research priority from consultation through the British Orthopaedic Foot & Ankle Society (BOFAS) (the establishment of clinical equipoise within the community). The orthopaedic trial comparing arthroplasty and arthrodesis surgeries was setup to answer this call for evidence as a non-inferiority study. When principal investigators in this qualitative study were asked what they expected to find, recruiting surgeons reported the trial would not show "dramatic differences in outcomes" in relation to pain and functionality in the short term. These views suggested, prima facie, a good likelihood of clinical equipoise at the level of individual surgeons.

Interviewees discussed reasons that compromise individual equipoise. First, the expectation that differences

between treatments would become evident in the longer term. They recognized the value of having a randomized patient cohort such as the one in this trial. This cohort's follow-up data would be essential to provide high level evidence about the superior clinical approach. It would also show the cost-effectiveness of treatments for ankle arthritis at ten- to 15-year follow-up. Although the study has planned long-term follow-up built in, the primary outcome measure was a clinical outcome score after one year, which to some investigators seemed less important. This also demonstrates the discordance between funders, who need cost-effective trials with quick answers, and surgeons, who want to study long-term benefits.

Second, randomizing patients to two treatments was unusual because most surgeons have experience participating in non-randomized observational cohort studies. The unease of this process was in part intensified by recruiters' experiences of patients preferring arthroplasty to fusion almost exclusively. Furthermore, some recruiters seemed uncomfortable with the trial mandate to be willing to perform both procedures. The balance between some surgeons' procedure ratios had been altered by participating in the trial. A surgeon said, "We do not consider ourselves ankle arthroplasty surgeons anymore. We are discussing treatment options". Previous research has shown that role conflicts such as those expressed in this study could influence the level of clinician engagement in trial recruitment.<sup>6</sup>

**Solutions to recruitment challenges employed by research teams in this RCT.** Recruiting teams had to deploy resources to follow-up patients over a long period of time. RAs became a "key contact" for prospective participants and strived to build trustworthy relationships with patients at sites that recruited well. For example, RAs would answer patient questions directly, without referring to other professionals, and would offer specific details about their availability. RAs reported that individualized close contact with patients helped them to trust the surgeon and team around them. Patients were then more likely to consider participation in the RCT. However, not all sites had RAs who were able to provide the level of engagement and support compared to the centres that recruited well. For example, participant information sheets were posted to prospective participants by an administrator in site C. Some RAs could not answer patient questions; instead, they signposted patients to either physiotherapists or surgeons.

Recruiters reported several strategies that helped return patients to equipoise in their recruitment consultations. They noticed patient preferences often lacked rigidity and tended to evolve during discussions with recruiting surgeons. For example, in a consultation between a recruiting surgeon and a patient who was considering surgery, the patient stated a preference for arthroplasty early on. The recruiting surgeon gently

### Box 1. Example of recruiter rebalancing treatment information

"(...) An ankle fusion basically converts what you've got right now which is a painful stiff joint into a painless stiff joint and actually it's the pain that's ruining your life at the moment, it's not the stiffness because you've got the stiffness. So actually, with an ankle fusion it would get rid of the pain and would allow you to do virtually everything that you said to me you wanted to do before.

An ankle arthroplasty basically resurfaces the joint and puts a false joint in there and I think that would get rid of your pain. The difference between an arthroplasty and a fusion is the arthroplasty retains motion whereas in a fusion, the two joint surfaces become one, but because you have thirty other joints or so in your foot that all still move, you may not notice a difference in terms of range of motion between a fusion and an arthroplasty. In other words, the range of motion may be the same and your function may be the same with both treatments" (PI, site C).

tested the reasons for their preference, discovering they were based on unverified information from websites. The surgeon was careful not to contradict the patient, saying, "and I think there is some truth in everything you've been told", but then suggested general applicability of information must always be secondary to individual diagnosis. Then the recruiting surgeon proceeded to rebalance risks and benefits of the two surgeries as shown in Box 1. Similar rebalancing strategies were observed from other recruiters in relation to recovery times, surgical outcomes and need for further intervention after either treatment. However, deploying these strategies depended on the treating clinicians being able to "build up the relationship with the patient" and show they were in "genuine equipoise".

### Discussion

This study has provided qualitative information about barriers to recruitment to an orthopaedic RCT. Recruiters faced four common obstacles when recruiting to a surgical orthopaedic trial: patient preferences for the intervention arm; complex recruitment pathway; logistical issues; and conflicting views on equipoise. The trial finished recruiting its target sample after a funded extension. Most successful recruiters were observed deploying strategies to overcome recruitment difficulties such as extended follow-up of potential participants and offering information to rebalance treatment perceptions, fostering patient equipoise.

The results of this study should be considered in the context of some limitations. Participants chose to take part in this study. Interviewers' views represent a highly motivated sub-group of the total of recruiters involved in the trial. Although methods from the QuinteT intervention were employed, this was in an abridged version.<sup>12</sup> This version did not contain a phase for planning and

implementation, where knowledge about recruitment barriers provided the basis for a plan of action. However, the qualitative findings were disseminated in an investigators' meeting and messages were reinforced by the trial team until the successful end of the recruitment period.

Delivering the highest quality of evidence depends on achieving the target sample of an RCT on time and within budget. Nevertheless, these findings support previous research on how complex trials present common challenges. Two issues appear central in these results. First, it emerged that relying on a group of dedicated research nurses capable of following-up potential participants for long periods of time was unsustainable in a multicentre trial. This is because of differences in staffing levels, staff turnover, and heterogeneity in departmental organization. Consequently, centres in this trial varied widely in their contribution, often with a non-linear relationship to staffing levels.

Second, previous research carried out by the trial team demonstrated orthopaedic surgeons have a key role in shaping treatment preferences in this patient group,<sup>13</sup> and this study confirmed that uncertainty within the community and the need for high-level evidence can be insufficient enabling factors for some surgeons to discuss a trial with clinical equipoise to patients. Surgical trials can polarize attitudes toward the interventions that are being compared.<sup>14</sup> Patients and clinicians tend to readily accept the risk-versus-benefit balance in trials comparing only minor changes to the same surgical procedure. They may not accept the balance on those trials where different approaches to surgery or different skill sets are required, and even less so when the alternative is a non-surgical intervention.<sup>14</sup> Our findings suggest the trial pertained to those that were difficult for patients and surgeons to accept. Indeed, as in many other challenging trials, strong patient preferences were considered one of the main barriers to recruitment to surgical trials.<sup>2</sup> Furthermore, as surgeons are now trained to share their decision-making with patients, it is possible that investigators in this cohort found recruiting to RCTs incompatible with this ethos as suggested by Sibai et al.<sup>15</sup>

A high staff turnover, combined with a tendency for patients not to enter in to surgical RCTs,<sup>16</sup> creates delays in recruiting enough participants, leading to costly extensions or closure of trials.<sup>17</sup> Addressing barriers to recruitment in clinical trials is of considerable interest for many medical specialities, particularly in orthopaedics, where surgery is usually one of the interventions.<sup>18</sup>

The most striking finding from surgeons interviewed was that, although they were hoping for the trial to show superiority of one treatment arm over the other, their real feeling was that the trial would not show a difference based on clinical score as the primary outcome

measure. It is perhaps this realisation that the equipoise they do indeed have, as demonstrated by their impression that the study would not show a difference, is in fact inconsistent with what they hope the trial may find. This "conflict" between their own preference and perceived patient preference for the intervention arm, may go some way to explaining why they may have displayed some resistance to recruitment.

There are multiple ways of addressing these challenges to recruitment. One strategy is to select PIs that support the trial and for whom clinical equipoise is not an issue. However, we are unaware of reliable methods to determine who may or may not be in equipoise prior to commencing trial recruitment. Generally, this is a self-selecting process in which PIs volunteer to take part in clinical trials perhaps because they find them interesting or necessary. Furthermore, all PIs in this orthopaedic trial agreed there was sufficient 'community equipoise' to justify the trial in the first place. Equipoise issues that emerged during the trial recruitment period, and evident through interviews with a small selection of PIs, were difficult to address at this point, as it would be difficult to deselect principal investigators from the trial team.

Another strategy is to address communication challenges by providing training to PIs and RAs on the specific skills of conducting trial recruitment consultations. Previous research has shown that routine research-driven consultations differ in important ways from routine clinical consultations.<sup>5</sup> Complex aspects specific to RCTs, such as randomization and equipoise, require careful explanation to patients. Patients with difficult questions need to engage with an individual with the expertise to answer those questions (i.e. orthopaedic surgeon). Indeed, successful recruiters in this trial modified their approach to patients providing balanced information about the two surgeries that were compared. There is evidence that training can be designed and implemented in orthopaedic surgical trials. For example, the QuinteT intervention was applied to the Full Randomised Controlled trial of Arthroscopic Surgery for Hip Impingement versus best Conventional (FASHIoN) trial,<sup>19</sup> and a six-step model to optimal recruitment became a training tool for recruiters to organize information giving to patients during the trial.<sup>20</sup> Patients tend to decline trial participation when trial specific concepts are not clearly explained, treatment arms are not described in a balanced way, or patient preferences are not explored.<sup>11</sup>

De Salis et al<sup>21</sup> has recommended that qualitative research should be embedded at an early trial stage to fully realize the potential recruitment benefits. However, we have shown that ongoing trials with recruitment difficulties can benefit from qualitative research conducted to understand barriers and opportunities. Embedding

qualitative research within a RCT works as a mechanism to disseminate good recruitment practices and foster a research culture.<sup>7,20</sup> This type of research also helps to evaluate cases where surgeon involvement may provide a net benefit to recruitment and prompt (re)calibration of roles within each recruiting site based on preliminary and ongoing outcomes.<sup>5</sup>

In conclusion, the present study has identified and reinforced known barriers to recruitment into orthopaedic trials. Careful study design, focus on equipoise, balanced materials and information to patients, and staff training are essential requirements for clinicians and trialists to consider when designing and conducting orthopaedic trials. Embedded qualitative research can contribute to elucidate recruitment barriers, and, if applied early, can be used to consider eligibility pathways and develop training for healthcare practitioners involved in the running of trials. We recommend the use of a mixed methods approach from trial set-up and ongoing management that can contribute to mitigation against recruitment failure and improve patient informed consent and participation.



### Take home message

- Qualitative research methods were rapidly deployed to identify recruitment barriers in a large multicentre surgical trial. Findings enabled the trial management team to address obstacles in an effective and timely manner.
- Our findings confirmed previous research that demonstrated orthopaedic surgeons have a key role in shaping treatment preferences in this patient group.
- Uncertainty within the scientific community and the need for high-level evidence may be insufficient enabling factors for some surgeons to discuss a trial with patients.
- The study added to evidence on trial conduct in orthopaedic surgery that can contribute to mitigate against recruitment failure and improve patient informed consent and participation.

### Supplementary material



Interview guide for Total Ankle Replacement Versus Arthrodesis (TARVA) trial recruiters.

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#### Author contributions:

- A. X. Realpe: Designed the qualitative study, revised and approved the manuscript.
- J. Blackstone: Ran the orthopaedic trial, Revised and approved the manuscript.
- D. R. Griffin: Designed the qualitative study.
- A. J. F. Bing: Ran the orthopaedic trial, Revised and approved the manuscript.
- M. Karski: Ran the orthopaedic trial, Revised and approved the manuscript.
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- M. Siddique: Ran the orthopaedic trial, Revised and approved the manuscript.
- A. Goldberg: Designed the qualitative study, Ran the orthopaedic trial, Revised and approved the manuscript.

#### Funding statement:

- Although none of the authors has received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the sub-

ject of this article, benefits have been or will be received but will be directed solely to a research fund, foundation, educational institution, or other non-profit organization with which one or more of the authors are associated. The study had been funded by the Health Technology Assessment Programme (HTA) of the National Institute of Health Research, this is a division of the department of health. Grant numbers 12/0518 and 12/35/27. Primary Registry and Trial Identifying Number: IS-RCTN60672307.

#### ICMJE COI statement:

■ D.R. Griffin reports grants from the National Institute of Health Research (NIHR) during the conduct of the study, and personal fees from Stryker UK, outside the submitted work; he is also a board member of the International Society of Hip Arthroscopy and is a consultant surgeon who routinely performs hip arthroscopy. A. Goldberg reports grants from the National Institute of Health Research (NIHR) during the conduct of the study, and personal fees from Wright Medical, outside of the submitted work. A. J. F. Bing receives personal fees from Wright Medical & MattOrtho outside of the submitted work. S. A. Milner receives personal fees from EIDO Healthcare, outside of the submitted work. M. Karski receives personal fees from DePuy Synthes and Wright Medical outside of the submitted work. All other authors declare no competing interests.

#### Data sharing:

■ The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

#### Acknowledgements:

■ \*The Total Ankle Replacement Versus Arthrodesis (TARVA) Study Group consists of: Stephen Bendall, Andrew Bing, Chris Blundell, Rick Brown, Clifford Butcher, Michael Butler, Tim Clough, Paul Cooke, Nick Cullen, James Davenport, Mark Davies, Sunil

Dhar, Andy Goldberg, Paul Halliwell, Bill Harries, Stephen Hepple, Raj Kakwani, Mike Karski, David Loveday, Nilesh Makwana, Steve Milner, Viren Mishra, Andrew Molloy, An Murty, Martin Raglan, Benedict Rogers, Mark Rogers, Malik Siddique, Dishan Singh, Rob Smith, Rhys Thomas, Paulo Torres, Dave Townshend, Matt Welck, Ian Winson, Prof. Justin Cobb, Prof. Mike Hurley, Prof. Linda Sharples, Prof. Amar Rangan, Dr Stephen Brealey, Prof. Marion Campbell, Prof. Alison McGregor, Prof. Nachiappan Chockalingam, Prof. Hamish Simpson, and Mr Nick Welch.

The authors wish to acknowledge support from hospital trusts, Local Clinical Research Networks (LCRNs), and collaborating surgeons, research associates and patients who gave so generously of their time and agreed to participate in the RCT. They would like to thank to the other members of the TARVA trial management group for their essential contribution: Deidre Brooking, Karen Alligan, Marion Cumbers, Paul O'Donnell, Liz Dean, Miriam Pollard, Iva Hauptmannova, Caroline Dore, and Simon Skene. The views expressed are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research, or the Department of Health.

#### Ethical review statement:

■ The study received Ethical approval from London Bloomsbury Research Ethics Committee (14/LO/0807). All participants received a participant information sheet and signed a consent form.

#### Open access funding:

■ The research for this paper was funded by an NIHR HTA grant (number 12/35/27).

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