Health and Social Care Delivery Research

Synopsis

Barriers to and outcomes of unspecified kidney donation in the UK: BOUnD, a mixed-methods study

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Abstract

Background: Unspecified living kidney donation, where an individual donates a kidney to a stranger, is practised in very few countries. Since the Human Tissue Act 2006, the practice has been increasingly prevalent in the United Kingdom. However, evidence exists of uncertainty from healthcare professionals as to whether this is appropriate or manageable.

Objectives: The Barriers and Outcomes in Unspecified Donation study is a mixed-methods study designed to determine the answers to three research questions:

RQ1. Is there variation in transplant professionals' practice and attitudes, which is preventing some unspecified donations?

RQ2. Are psychosocial and physical outcomes after unspecified donation equivalent to those after specified donation?

RQ3. What is the economic benefit from unspecified donation?

Design: For RQ1, a qualitative study of healthcare professionals using focus groups and interviews was performed. Additionally, a quantitative, questionnaire-based study, including healthcare professionals from all United Kingdom transplant centres, was carried out.

For RQ2, a qualitative study of unspecified kidney donors, including those who did not donate, was performed. A prospective, questionnaire study of both specified kidney donors and unspecified kidney donors across the United Kingdom was completed, and linked to data recorded by National Health Service Blood and Transplant.

For RQ3, data on utilisation and quality of life were collected pre- and postoperatively using health economic and quality-of-life questionnaires to allow calculation of costs and comparisons between unspecified kidney donors and specified kidney donors.

Results:

RQ1: Fifty-nine interviews were conducted with healthcare professionals at six United Kingdom centres. There was broad support for unspecified donation, but key themes included the need for further training and information, consistency in approach across the United Kingdom, and uncertainty about age limits and psychological assessments. Managing donor expectations was a major concern.

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One hundred and fifty-three healthcare professionals, from all 23 United Kingdom transplant units, were recruited into the questionnaire study. The themes above were confirmed, and the need for more resource, particularly training and staffing, were emphasised.

RQ2: Eight hundred and thirty-seven participants including (59.3%) specified kidney donors and (40.7%) unspecified kidney donors were recruited to the prospective questionnaire study, of whom 373 went on to donate. We found no difference in psychosocial or physical outcomes, withdrawal rates [hazard ratio: unspecified kidney donors vs. specified kidney donors 1.12 (95% confidence interval 0.75 to 1.67)] or regret, although unspecified kidney donors experienced fewer positive perceptions [specified kidney donors 319 (86.2%) vs. unspecified kidney donors 247 (79.9%); $p = 0.034$].

In the qualitative study of 35 unspecified kidney donors (15 donated, 20 withdrawn), we found evidence of psychological distress in those not proceeding to donation, with a need for consistency and management of expectations.

Data from the RQ2 prospective study showed a wide variation in withdrawal rates of donors across the United Kingdom, with withdrawal less likely in high volume, well-staffed centres. Fifty-eight per cent of unspecified kidney donors came from just five centres.

RQ3: We found no difference in costs between the two groups (£937 vs. £778; ns). We calculated that a 10% increase in unspecified kidney donors nationally would save at least £5 million.

Conclusions: This study suggests that unspecified donation is a safe and acceptable practice. Training and information should be disseminated across United Kingdom centres, with increased resource for unspecified donation where necessary. Consistency in approach and support for donors who do not proceed is important.

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Introduction

In 2006, the UK Human Tissue Act introduced a legal framework for unspecified donation; that is, donation of a kidney from a living individual to an unknown recipient (also known as 'altruistic' or 'non-directed' donation).[1] The first unspecified kidney donation (UKD) took place in 2007, after which the numbers increased rapidly. UKD now forms between 8% and 10% of the living donor programme in the UK.[2] Despite increased activity in the UK, the practice remains illegal in many countries. Those permitting and supportive of UKD include Australia, Canada, the Netherlands, New Zealand, South Korea and the USA. It is also legal in Italy, Spain and Sweden; however, it is relatively uncommon and not actively promoted.[3] Within the UK, there were both anecdotal and some published evidence that candidates for unspecified donation faced barriers due to concerns expressed by some members of the healthcare teams,[4] in a similar fashion to the opposition to living donation experienced some two decades earlier.[5]

Living kidney donation

Living kidney donors undergo major surgery, with a mortality rate of 1 in 3000 and a major complication rate of around 5%,[6] for no physical benefit to themselves. When donating to a friend, relative or someone they know (known as specified kidney donation), it could be argued that benefit lies in seeing somebody they know benefiting from a kidney transplant. Living kidney donation is a highly successful operation, with 1-year graft survival rates of 98%,[2] and an expected median graft survival of 25–30 years. Nevertheless, objections were raised in the noughties as the practice developed, with concerns about the ethical nature of such a practice.[7] Today, living donation is the norm in most developed countries and is considered the treatment of choice for end-stage kidney failure.

Objections to unspecified donation

Early data on UKD in the UK demonstrated that donor activity was concentrated in certain centres, predominantly across the South of England.[8] In 2013, 45% of all UKDs in the UK were performed in just 3 of the 23 UK kidney transplant centres. Anecdotal evidence upon discussions with colleagues revealed a significant level of opposition to the practice, with concerns that the act of UKD was indicative of underlying psychopathology. Additionally, many felt that the practice could not be ethically justified, since there is no benefit to the donor and that the principle of non-maleficence ('first do no harm') would therefore be violated.[9] Published evidence on the attitudes of healthcare professionals was lacking, although one study found that 78% of French physicians were opposed to the practice,[10] and further misgivings have been detailed in other small studies.[11–13] However, there is clearly a lack of significant evidence on the attitudes of healthcare professionals to UKDs. In terms of psychopathology, healthcare workers have sometimes expressed the view that unspecified kidney donors were 'mad, bad or sad'[14]; that is, that the desire to donate reflected a psychological or personality disorder, or that they had undergone a traumatic life event which provoked the need for atonement or, perhaps, self-harm.

There was some limited evidence that UKD candidates experienced difficulties because of these attitudes. One qualitative study found that scepticism and resistance could be encountered from healthcare professionals, or indeed from within a family, and concerns were raised about having to prove their sanity as part of a formal mental health assessment conducted prior to being accepted as a donor.[4] While it has never explicitly been a legal requirement for UKDs to undergo a mental health assessment, this has always been considered best practice.[15] This is not the case with specified kidney donors (SKDs), who undergo assessment at the discretion of their clinical team. Some centres routinely send all donors for a formal mental health assessment, whereas others do not.

Guidance and resource

Some unpublished qualitative work has shown that living donor assessors and co-ordinators are concerned about the lack of practical guidance for dealing with UKDs,[13,14] which is not adequately covered by existing guidelines[15] and focuses predominantly on SKDs. Currently, there are no guidelines on assessing UKD worldwide, although a North American group 20 years ago commented on approaches to 'unrelated' donors, which do not match the current concept of UKDs.[16] A psychosocial assessment tool for use in all donors has been devised and piloted by the Ethical, Legal and Psychosocial Aspects of Transplantation (ELPAT) section of the European Society for Organ Transplantation, which provides both a questionnaire guide and interview schedule to help mental health and transplant professionals undertake a psychosocial assessment of donors before donation.[17] There are some reports of high dropout rates during the assessment of UKDs,[18,19] and our own analysis prior to this study showed that 64% of UKDs contacting one UKD centre did not proceed to donation. This had led to concerns that when compared with SKDs, UKDs require more resource but for less gain.

Utilisation of unspecified kidney donors

A kidney from an unspecified donor can be used in a few different ways.[20] The organ may be directed to a recipient from the deceased donor waiting list using a standard computerised algorithm, or may be used to 'prime' paired donation from a kidney sharing scheme (KSS), where recipients who are incompatible with their donors receive a kidney from another donor (*Figure 1*).[21]

Donor–recipient pairs may be incompatible with each other for reasons such as blood group or due to the presence of antibodies in the recipient against the donor. Donor chains may be in the form of 'short' (typically two recipients) or 'long' (three or more recipients) chains, with the final organ going to a patient from the waiting list. When the surgery is carried out non-simultaneously, these are known as non-simultaneous extended altruistic donations. There is some evidence from computer simulations that such donations facilitate around double the number of transplants when compared with donating to the waiting list,[20] although the data were not definitive. It should be noted that patients in a KSS are those who are typically harder to transplant, that is, for immunological reasons, some of whom can expect a long or indefinite wait. There is therefore potential for UKDs to provide a high-quality organ to facilitate multiple transplants for those who would otherwise have a low chance of transplantation, and for this reason, over the last 4 years, UKDs have been asked to enter the KSS in the UK, should they not be matched with another higher priority recipient. There are disadvantages to the donor, however, since the KSS conducts a computerised allocation 'run' every 3 months, with the expectation that resulting matches would result in transplantation being carried out within a subsequent 8 weeks. This may mean that a UKD who is ready to donate could wait several months for surgery and, even then, may face further delay if a simultaneous chain breaks down at the last minute (e.g. if one patient is unwell).

Given the concerns about the motivations and potential psychopathology of UKDs, there is clearly the possibility that they might show poorer outcomes after donation when compared with SKDs. However, very little data exist. We carried out the largest quantitative study of UKDs, where we retrospectively analysed 148 UKDs and compared them with 148 SKDs.[8] We found no difference in physical or psychosocial outcomes in the two groups, but the obvious issue was that those with significant pathology might be less likely to respond, so this may have been under-reported. Similar findings were reported in a smaller study of 39 UKDs from the USA.[22] These were quantitative studies, using standardised psychometric assessment tools, but a limited amount of qualitative work has also been performed.

Qualitative studies of unspecified kidney donation

Clearly, understanding the motivations or psychological outcomes of UKDs is difficult from a simple set of psychometric forms, and a more detailed approach would seem beneficial. This would imply a qualitative approach; however, only a limited amount of work has been done. A Dutch group conducted interviews at several time points, both pre and post donation, in 151 donors, only 16 of

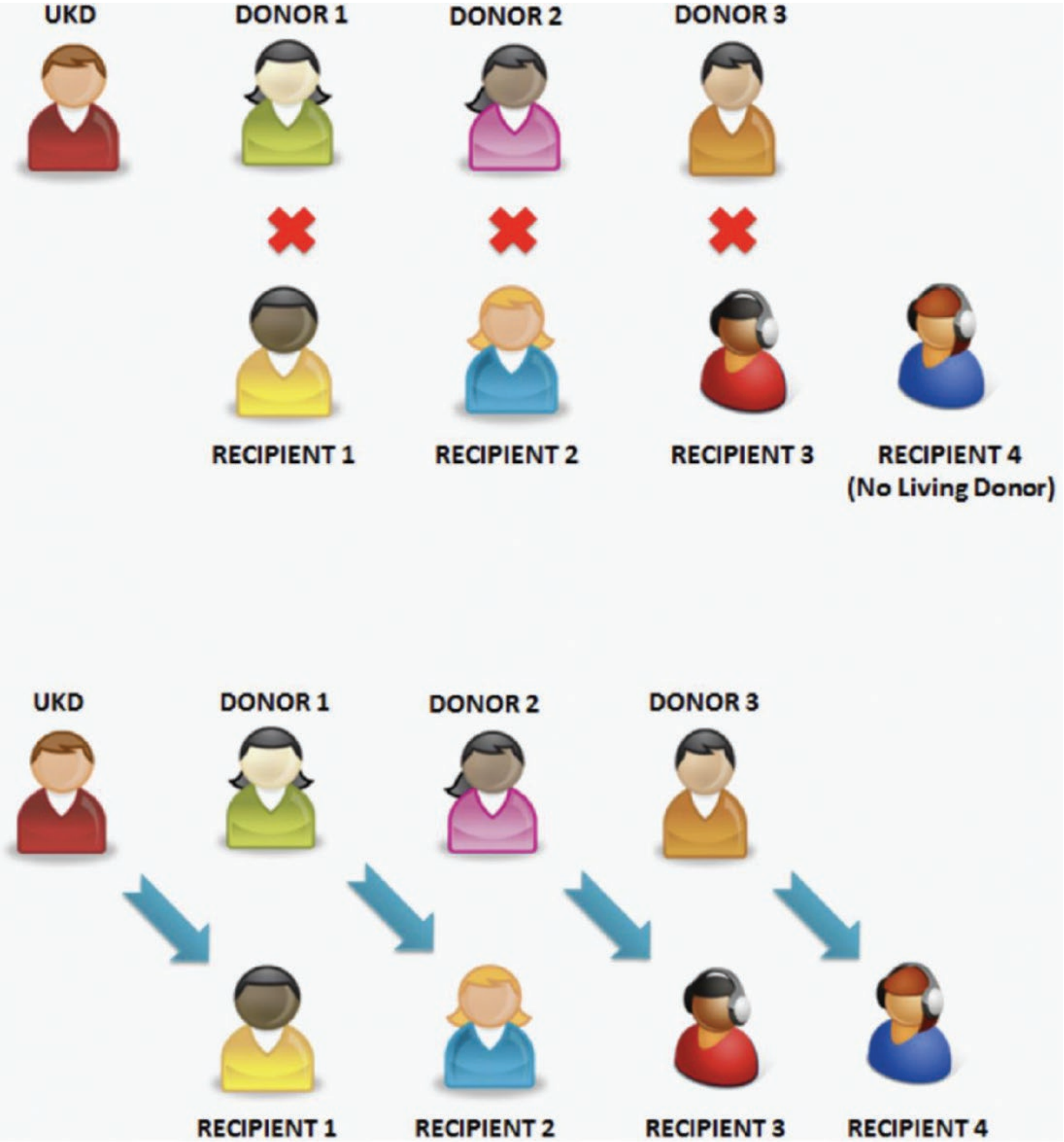


FIGURE 1 An example of a chain primed by a UKD. Reproduced from Gare *et al.*[21] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/.

whom were UKDs.[23] This study found that there was no difference in physical or psychological outcomes when compared with SKDs.

A group from the University of Plymouth, who collaborated in Barriers and Outcomes in Unspecified Donation (BOUnD), previously interviewed 14 UKDs at 4 UK transplant centres, and found that 2 main themes emerged: 'connected to others', where the motivations were found to be genuine and positive, and 'uneasy negotiations with others', which highlighted difficulties in dealing with both healthcare staff and in other relationships during the donation process.[4] Another Dutch study, where 24 UKDs were interviewed some 2 years after donation, found that donation had had a positive impact on their lives, and that psychological issues did not appear to be higher than expected.[24]

The economics of unspecified kidney donor

Kidney transplantation is widely considered to be better for the patient with end-stage renal disease when compared with dialysis, not only in terms of patient mortality and morbidity, but also economically. Several studies have shown transplantation to be cost-effective.[25] Living donation is particularly beneficial, since the waiting time for the recipient is reduced, surgery is performed electively during 'normal' hours, and a large organ retrieval team, with the associated disruption to the donor hospital, is not necessary. However, little is known about the cost–benefits of UKD specifically and what contribution it makes financially to living donation as a whole. As described above, it may be that UKDs are more resource-intensive than SKDs, with a higher dropout rate. If there were more psychopathology postoperatively, this would also constitute an increased cost. Nevertheless, the utilisation of UKDs to prime transplant chains and facilitate multiple transplants, in particular for those patients who would be likely to spend a long time on the waiting list, may mean that any extra costs are justified. In 2018–9, a total of 64 UKDs primed chains in the UK KSS, resulting in 134 transplants.[26] To put this in context, around 900 living donor transplants are performed annually in the UK. To date, we have been unable to find studies assessing the cost–benefit of UKD.

Rationale for this research

In summary, there is a large gap in our understanding of UKD.[27] We remain uncertain about the motivations of UKDs, and whether they are more likely to develop psychopathology after donation when compared with SKDs. We know that some healthcare professionals are uncomfortable or opposed to the practice of UKD, but we do not know how widely or profoundly such views are held. Professionals appear to want more guidance, but we are uncertain whether UKDs require more resources than usual. We do not have definitive data on the best use for a kidney from a UKD – it appears that utilisation to prime a chain in a KSS is cost-effective, but studies are lacking, and we do not know how much 'value' such a kidney generates. This is particularly important when considering whether increased resources are necessary for UKDs. In the first decade of this century, central funding was made available to pump-prime living donor programmes (for SKDs), which resulted in a rapid and very significant rise in living donation, in large part by funding specific living donor co-ordinators. It may be that a similar approach could be taken with UKDs.

For these reasons, the BOUnD study was set up, with several specific aims. It adopted a mixed-methods approach, allowing for gathering of quantitative data from across the country, supported by more detail provided by qualitative methods.

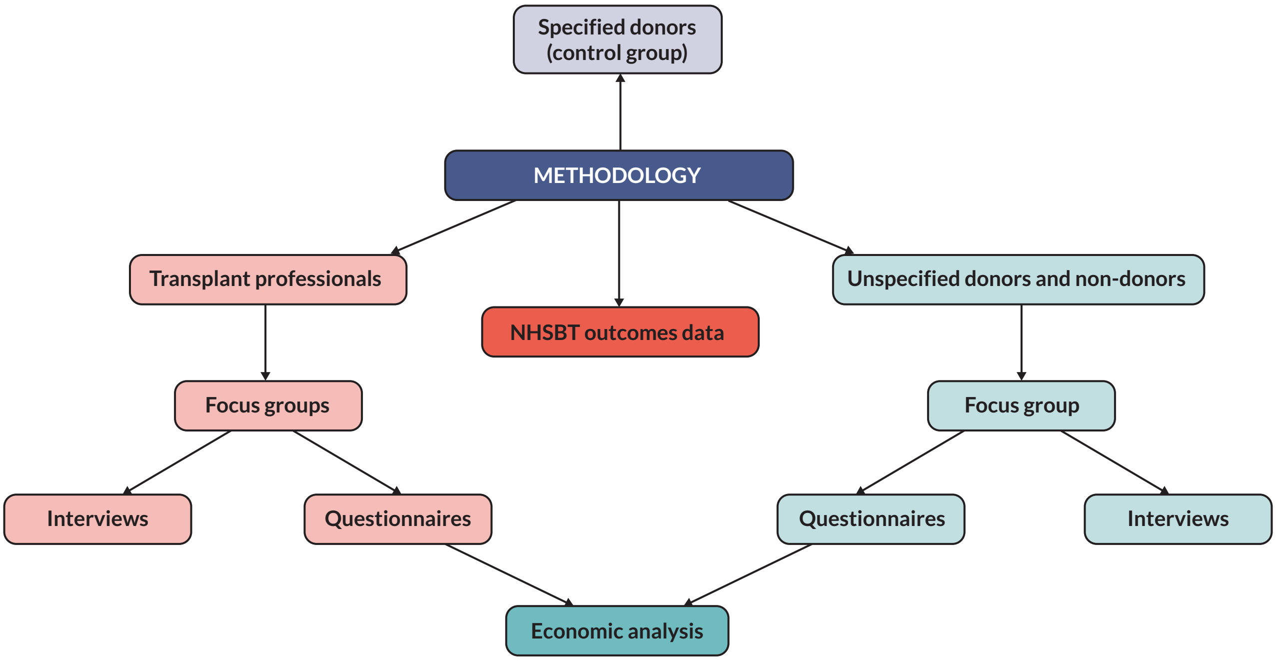
Aims

This study aimed to provide a comprehensive, prospective assessment of the UKD programme in the UK. There are three specific research questions:

RQ1. Is there variation in transplant professionals' practice and attitudes, which is preventing some unspecified donations?
RQ2. Are psychosocial and physical outcomes after unspecified donation equivalent to those after specified donation?
RQ3. What is the economic benefit from unspecified donation?

Research pathway diagram

The below figure is reproduced from a published manuscript which described the methodology of the study.[21]



Methods

The study adopted a mixed-methods approach to answer the three research questions listed above. A detailed description of our methodology was published in 2017 in *BMJ Open*.[21] In summary, the approach to both study populations (transplant professionals and donors) began with focus groups to provide an up-to-date perspective on the most pertinent issues and to understand what gaps in the existing literature needed to be filled.

For the transplant professionals group, four focus groups were conducted – two in centres performing relatively high numbers of UKDs and two in centres performing relatively low numbers. The purpose of this was to identify key cultural trends between the two groups and to understand the topics justifying further broader investigation in the quantitative study. The data from these focus groups were subjected to thematic analysis, and the key themes were extrapolated. A purposively designed questionnaire was written, validated and subsequently piloted prior to being disseminated across all 23 kidney transplant centres in the UK. This is the only comprehensive study to have ever been performed with the sole purpose of exploring the views of transplant professionals towards UKD.[28] Data were captured on different aspects of UKD, including personal experiences, broader attitudes towards organ donation, and specific concerns about UKD. One hundred and fifty-three responses were obtained, with representation from all UK centres and professional groups.

To enrich the data collected from the quantitative study, and to help provide explanations behind some of the results obtained, an in-depth qualitative study was also conducted. Fifty-nine individual professionals, from three high-volume and three low-volume UKD centres, underwent one-to-one in-depth interviews directed by a topic guide. The results of these studies were published in the journal *Transplant International*[28,29] and are discussed below.

For the living donor groups, two focus groups were held, including those who had been unspecified donors and those who had embarked on the assessment process but failed to donate. The details of these focus groups are provided in *Appendix 2*. The results of these focus groups informed the quantitative aspect of the second and third research questions mentioned above and a further qualitative in-depth interview study of donors who had not proceeded to donation. As above, for the transplant professionals group, a purposively designed questionnaire was written, validated and subsequently piloted prior to being disseminated. An 'acceptance of Unspecified kidney donation' score was created from some selected items in the questionnaire. The psychometric data for this are provided in *Appendix 4*.

For the prospective donor study, we recruited 837 donors from across the UK. Physical and psychological outcomes were collected using validated questionnaires (via an online platform) up to 1 year following donation or withdrawal from the donation process. We utilised a longitudinal cohort design with four intervention time points: (1) baseline (at recruitment), (2) pre donation (2–4 weeks before surgery), (3) 3 months post donation and (4) 12 months post donation. A matched sample of specified donors (those donating to someone they know) were recruited as a control group. Our data were matched with mandatory registry data from NHS Blood and Transplant (NHSBT).

To answer the third research question (health economic aspects of UKD), we collected data on the utilisation of healthcare resources, again using validated questionnaires, to compare the costs of unspecified and specified donation. Service use was measured using the Client Service Receipt Inventory (CSRI). The CSRI asked participants for details of services used in the 6 months prior to baseline and then the period up to pre-operation assessment, 3-month follow-up and 12-month follow-up. Information was collected on how many contacts took place and, for some services, what the typical duration was. For inpatient care, information was collected on number of days spent in hospital.

We have included the relevant questionnaires, along with information about design, as supplementary material (see *Report Supplementary Material 1*). Ethics approval was granted by the South Central-Berkshire B Research Ethics Committee (15/SC/0637). The trial registration number is ISRCTN23895878.

Discussion

Principal findings

The BOUnD study aimed to provide a comprehensive assessment of the UKD programme in the UK, and set out with three specific research questions:

RQ1. Is there variation in transplant professionals' practice and attitudes, which is preventing some unspecified donations?
RQ2. Are psychosocial and physical outcomes after unspecified donation equivalent to those after specified donation?
RQ3. What is the economic benefit from unspecified donation?

We believe we have achieved such an assessment and have answered each of these questions by performing the largest and most detailed study of UKD to date. All 23 transplant centres in the UK participated. We recruited a large and representative range of healthcare professionals and 837 donors. Two large qualitative studies of professionals and donors were performed. The findings are summarised below, and where appropriate, the results of both the qualitative and quantitative components of the study have been synthesised.

Is there variation in transplant professionals' practice and attitudes, which is preventing some unspecified donations?

Our questionnaire study (RA3) was the first quantitative study to report systematically on acceptance by transplant professionals of a large national UKD programme. It found that while a large majority of transplant professionals supported the concept of UKD, the practice remained challenging for several reasons. These were also reflected in the qualitative study, which identified five main themes: staff's conception of the ethics of UKD; presence of the known recipient in the donor–recipient dyad; need for better management of patient expectations; managing visceral reactions about the 'typical' UKD; complex attitudes towards a promising new practice. The results from both studies complemented each other well and provided detailed insights into the challenges of UKD, and the potential barriers in expanding the programme.

One area of regularly debated contention is that of donor age, which anecdotally has been a significant cause for concern primarily in relation to allowing young adults to donate (due to the donor needing to live the rest of their life with only one kidney). Currently, no legal age limit exists for any form of living donation, but the lowest age is commonly accepted as 18. In the questionnaire, participants were specifically asked about both upper and lower age limits for UKD. The majority (77%) felt that a lower age limit should apply to UKDs, with the most common suggestion being 25 years. The suggested range of ages was also very broad (16–50), which provides an insight into how strongly some transplant professionals may feel regarding this issue.

In the qualitative study (RA4), the issue was explored and found to be rooted in concerns regarding the ethical aspects of living donation; that is, that it goes against the primary principle to 'do no harm'. While all living donation conflicts with this principle, this is amplified in UKD due to the donor not knowing their recipient. The benefits of donation (required to justify the harm of one person for someone else's benefit) are therefore more difficult to understand and consequently alters the balance between harm and benefit. This suggests that concerns regarding donor age (and likely other issues related to UKD, such as psychopathological motives) are not rooted in malice or a desire to be obstructive. It is more likely that transplant professionals are attempting to understand how a new and controversial practice fits in with their own moral principles, and the ethical principles that underpin their profession. This further supports the whole aim of the BOUnD study to not only provide insights into these behaviours but to also support healthcare professionals by providing high-quality data on outcomes. It is imperative that when moving UKD forwards, a focus is placed on training healthcare professionals appropriately with robust and high-quality evidence base.

Anonymity has also been a hotly debated topic. In the qualitative study, participants suggested that some UKDs struggled with the requirement for anonymity, principally due to a strong psychological need for connection with the recipient, and there were some who maintained a degree of uncertainty about whether this provided a pathological motive for donation. The requirement for psychological assessment was strongly supported, and the need for consistency across units was a key theme. The issue of psychopathology was raised in both studies, with participants in the qualitative study further explaining how they struggled to understand donor motivations and how this also contributed to a strong desire for early psychological assessment. A large proportion of participants in the quantitative study (52%) stated that a formal mental health assessment should take place before any medical tests, which implies that they felt that this was likely to be the primary reason why UKDs would subsequently withdraw or be withdrawn from the process. Again, this was captured in the longitudinal donor study and was found not to be the case (please see below).

It was also acknowledged, however, that neither group of living donors were psychosocially unproblematic. For the SKD cohort, concerns were raised regarding complex family dynamics, the potential for donors to donate out of obligation and anticipated feelings of guilt and anxiety influencing decision-making. Participants also stated that while there was a significant effort to elicit motives in UKDs, perhaps not enough effort was made to explore the same in SKDs when perhaps it should.

Interestingly, the quantitative study found there was no variation in levels of acceptance between professional groups, but there was greater acceptance by those from higher volume centres. This is likely to be due to positive reinforcement from positive outcomes. However, the high-volume centres described some practical issues and a greater number of negative personal experiences. We hypothesise that these apparently contradictory findings may be due to already-busy living donor programmes being faced with a broader range of potential UKD candidates and increased demands on resources.

Most transplant professionals had positive experiences with UKDs, although a significant proportion found UKDs to require more time and perceived that they had higher dropout rates. This was reiterated in the qualitative study and was expanded upon, with participants stating that they felt some UKDs had unrealistic expectations about the entirety of the process, and that they wanted to have control in navigating the process. This was thought to possibly be due to inexperience with healthcare systems and how they work in practice, but also may reflect the strength of desire to donate and 'get on with it'. The latter point regarding withdrawal rates be perceived as higher in UKD again has been raised before, and definitive evidence to the contrary is presented below.

In RA5, we have reported data from donors who withdrew and found a wide variation in withdrawal rates across the UK. Higher volume centres, and those with more staff (in particular, living donor co-ordinators), had lower withdrawal rates. We did not find a difference in withdrawal rates between SKDs and UKDs when longer follow-up was included.

We analysed data comparing UKDs who withdrew with SKDs who withdrew, and this is presented in *Appendix 1*. Those dealing with higher numbers of UKDs, and those with more staff overall and, in particular, more co-ordinators for UKDs, had lower rates of withdrawal of UKDs. Interestingly, the high-volume UKD centres had lower rates of withdrawal of both UKDs and SKDs.

The rate of withdrawal in SKDs was lower than UKDs during early follow-up, but this difference had disappeared by 3 years. This could be due to slower workup for UKDs, more early medical withdrawals in that group, or because some SKDs are expedited to pre-emptively transplant the recipient (before the need for dialysis), although a significant number of withdrawals had no stated reason. Withdrawal rates were lower in older, more educated UKDs, and higher in the anxious and depressed. We found no evidence of a change in withdrawal rates during the pandemic. Unsurprisingly, UKDs had a shorter time from first contact to consent for the study, which likely represents enthusiasm for donation.

Are psychosocial and physical outcomes after unspecified donation equivalent to those after specified donation?

We reported data from a comprehensive, prospective study which included 837 participants (RA5), which is the largest study of UKD. Of these, 169 UKDs and 204 SKDs donated during the study period. Five transplant units contributed to 58% of the total study sample, with similar numbers of UKDs and SKDs recruited from these five units (see *Appendix 1*, *Figure 4*). These broadly align with the annual number of living donations taking place at the same centres.[2]

Over the same time frame, 334 UKD donations took place in total in the UK; therefore, we collected data on 51% of UKDs. UKDs were found to differ in some demographic details (more likely to be male, less likely to have religious beliefs) compared with SKDs and were more likely to have indulged in other altruistic behaviours. Although there were understandably some differences in motivations between the two groups, motivations for both were overwhelmingly positive, with no evidence of any inappropriate motivation among UKDs. For UKDs, the prompt to donate came mainly from the media. The majority in both groups felt that they had received a positive response from the clinical team, although this was slightly lower among UKDs (79.9% vs. 86.2%). We found that both physical and psychosocial outcomes were equivalent for UKDs and SKDs at 3 and 12 months after donation. Of note, there was no evidence of a difference in mental illness or distress between the two groups over the study period. This held true both for questionnaires completed by the participants and registry data obtained from NHSBT. This provides robust evidence to support the practice of UKD.

There was no difference in long-term regret between the two groups, but some evidence that UKDs experienced more negative perceptions, mainly from friends and family. This is important as educational interventions may help with this.

One of the most significant findings from this study is that there was no statistically significant difference in dropout rates (after enrolment in the study) between the two groups. It has been a commonly held belief within the transplant community that UKDs are more likely to withdraw from the process, possibly to being more unsure or having not thought about donation in enough detail. The lack of difference in withdrawal has significant implications in terms of cost and the investment of national and local resource.

In RA6, we reported the findings of a large qualitative study of UKDs, with the most important findings being that those who did not proceed to donation did suffer some ongoing psychological distress. The need for managing expectations and for a consistent approach between transplant centres was clear. Specifically, for those with new diagnoses, it is imperative that appropriate follow-up is arranged to help individuals process and adjust a new medical or psychological issue.

We have also reported the unpublished findings of two focus groups, one for UKDs who donated and one for those who withdrew or were withdrawn (see *Appendix 2*). These highlighted two psychosocial dynamic themes, responsibility and completeness, and identified the beneficial effect of anonymity in 'freeing' the donor from responsibility to the recipient. It also emphasised the importance of the donors' family in the process, with concern over subjecting the family to anxiety, as well as a need for family support.

There remains a broad difference in rates of UKD across the UK, with 58% of donations taking place in just five centres. UKD volume appears to be associated with living kidney donation volume, with those centres performing larger numbers of living donation contributing more to the UKD programme. This suggests that large volume centres for living donation may be more receptive, or have more resource for UKD, with the implication that either further resource should be provided across all centres, or consideration given to focusing UKD in a few.

What is the economic benefit from unspecified donation?

We have reported an economic analysis of unspecified donation in RA5 and *Appendix 3*. We found that there was no significant difference in the cost of UKDs when compared to SKDs. Pre-operative costs were £1858 for UKDs and £1824 for SKDs, and postoperative costs were £778 and £937, respectively. We calculated that a 10% increase in UKDs nationally would save the NHS at least £5 million. A large proportion of this is likely to be savings in dialysis costs. We investigated the economic benefit of using UKDs to prime chains within the National Kidney Sharing Scheme (NKSS) and found that if we assume an investment of £5 million to increase numbers, then an extra 50 unspecified donations would result in an incremental cost per quality-adjusted life-year (QALY) below £30,000 (the upper threshold used by NICE). Overall costs are very similar between both types of donors. Health-related quality of life is also similar for both groups, and the reduction in quality of life following donation is small. We can conclude from these analyses that there are no substantial cost-effectiveness implications of unspecified donation at the level of the donor. However, increasing unspecified donation may be highly cost-effective if it results in a chain of transplants.

Strengths and weaknesses of this study

The BOUnD study is the largest and most comprehensive study of unspecified donation to date. It has provided very useful data across many aspects of the practice. The results are supportive and provide suggestions for how existing barriers might be overcome. These are pertinent not only to the UK but also to the many other countries which do not currently perform unspecified donation. The mixed-methods approach has provided thorough evidence regarding both healthcare professionals' and service users' experiences, and the prospective study of donors is by far the largest performed. The strengths of this study also lie in its prospective longitudinal design capturing data from every transplant centre within the UK. The questionnaire designed for this study captured data on a range of factors pertinent to living donation, as identified by a focus group involving former donors. This study therefore provides a very comprehensive assessment of both the UKD and SKD population.

The limitations relate to the number of donors who were initially recruited who then did not proceed, and missing data when questionnaires were not completed. Changes within the allocation system for UKD kidneys occurred halfway through the study, which led to some delays in UKDs donating. The coronavirus pandemic also halted the living donor programme in the UK, which led to some UKD candidates not proceeding. We did not carry out individual interviews with SKDs, but our aim was to use the qualitative aspects to explore the experiences of UKDs in more depth, rather than make any comparisons between UKDs and SKDs, as the issues affecting SKDs were likely to be different due to the implications on the recipient who is known to them.

While this is the most complete study of unspecified donation, inevitably some data are missing. While all 23 UK transplant centres responded to the professionals' questionnaire, with 153 responses, those who are opposed to UKD may have been less likely to respond, and we acknowledge that this is a potential source of selection bias. The counterargument to this is that UKD has anecdotally been quite a divisive topic, with many transplant professionals holding strong opinions.

Therefore, those who felt very strongly against UKD may also have been more likely to respond as the questionnaire may have been perceived as an opportunity to voice concerns and opinions. We are hopeful that the results are sufficiently balanced and capture the full range of views on the topic.

Similarly, for the prospective donor study, not all donors responded to the follow-up questionnaires, and those who did not might have had worse experiences. This may introduce a degree of responder bias, with an artificial elevation in the more positive psychosocial outcomes reported by the study. The robust data from NHSBT on all participants' physical outcomes indicate that for these at least, we can be fairly certain that the practice is safe from a physical outcomes perspective. A further and broader comparison could have been made by requesting NHSBT data for all living donors over the study period, such that physical outcomes in the study sample could be compared with the wider donor population.

The mixed-methods approach to the entire study was intentionally divided into separate qualitative and quantitative studies, both of which were influenced and designed following focus groups which were conducted at the beginning of the body of work. We acknowledge that an alternative, more deliberate mixed-methods approach may have been utilised to explore the same topic. For example, the questionnaire responses provided in the transplant professionals' study (RA3) could have been used to guide an interview with the respondent to further build on the data acquired and to provide reasoning behind the answers provided. A similar approach could have been adopted for the prospective donor study. For the former, we wanted to ensure that transplant professionals had the opportunity to answer the questionnaire anonymously without being identified within a relatively small professional group. We accept that there may have been opportunities to circumnavigate this issue (i.e. the interviews being conducted by non-transplant researchers). Given the potential benefits of a more deliberate qualitative approach, we will try and facilitate this for future studies.

Challenges faced

Inevitably, the key challenge was the COVID pandemic, which meant that living donor transplantation ceased across most of the UK for much of that period. This had a very significant effect on recruitment rates for RQ2, for both SKDs and UKDs. Prior to the pandemic, there had been a small decline in UKD donations across the UK, which then plateaued, and it remains unclear why this occurred. As a result of these factors, several changes were made. Firstly, an aggressive recruitment campaign was instituted, with regular calls to transplant unit co-ordinators, an active social media recruitment drive and study meetings at transplant conferences. Secondly, an amendment to the protocol was made so that the original target of 224 UKDs proceeding to donation, and 400 SKDs, was amended to 137 and 187, respectively.

The statistical justification in the amendment was as follows:

> *The expected sample size has 80% power when the non-inferiority limit is set at a standardised mean difference of 0.38. The revised target of 137 prospective unspecified donors and 187 specified donors leads to has 80% power when the non-inferiority limit is set at a standardised mean difference of 0.32. The non-inferiority limit for the revised target sample size is more acceptable given that it is closer to the minimum important difference for the outcomes considered range between a standardised mean difference of between 0.3 to 0.4.*

An extension of 16 months to the study was requested and approved. We managed to recruit 837 participants, with 169 UKDs proceeding to donation and 204 SKDs proceeding to donation, thus exceeding our final targets.

All other recruitment targets were met or exceeded.

Engagement with partners

The study has been performed in collaboration with NHSBT (with a key member of the study team occupying a senior role in NHSBT), who have provided robust follow-up data, collected on a mandatory basis, which has ensured completeness. The involvement of members of the Give a Kidney charity (which promotes unspecified donation) and previous donors in the study team has provided a very useful users' perspective, and the study team has included a wide mixture of psychologists, qualitative researchers, an ethicist, surgeons and quantitative researchers.

Related work

We have detailed all outputs from the study in our publication protocol, which includes additional related work (a review on unspecified donation and an economic analysis of living donation).

Equality, diversity and inclusion

The project management team consisted, in our view, of a wide range of people from different backgrounds. Three were ethnic minorities, including the chief investigator, and there was an even gender split (five women, four men). At the start of the study, three of the healthcare professionals were lecturers, thus representing a more junior perspective, and three were professors (of surgery, ethics and economics). This team designed the three arms of the study, and focus groups of participants were used for both RQ1 and RQ2, to ensure that the issues relevant to the participants, as well as the study team, were addressed. These are described in RA4 and RA6. As detailed in RA3, a wide range of healthcare professionals participated in the quantitative study, with a preponderance of women, and 14% from ethnic minorities.

We describe the demographic data of donors recruited in RA5; our aim was to attempt to recruit every potential donor, and thus our sample has a very similar make-up to previously reported studies (e.g. a low representation of ethnic minorities among UKDs). As noted, we collected detailed data on 51% of all UKDs in the UK during the study period, as well limited data from NHSBT on every UKD, and thus we believe our sample reflects actual demography.

It is well known within the transplant community that individuals from ethnic minorities are less likely to donate, either as living or deceased donors. This is also reflected in this study, within which most service users were white and therefore this study sample is representative of the broader living donor population in the UK. Considerable efforts funded centrally and through other research awards are being made to address some of the issues behind why so few individuals from ethnic minorities donate, especially since those from ethnic minority communities are much more likely to need a kidney. The social, religious and cultural issues are well known and complex, and therefore fall outside of the scope of this project.

Patient and public involvement

We aimed to include this at every stage of the study, and therefore two service users (i.e. previous unspecified donors) were an integral part of the study team. They provided input on study design, for example, questionnaires, data analysis and interpretation, and are fundamental to our dissemination plan. One is also a representative of the Give a Kidney charity, which is run by previous unspecified donors with the aim of informing the public about all types of living donation. We therefore presented the study methodology and ongoing results at their annual meeting on several occasions.

Implications for decision-makers

Our study findings suggest that UKD is a safe practice, with excellent physical and psychological outcomes, and low levels of regret. Furthermore, we have shown it to be highly cost-effective, even with conservative estimates. Transplant healthcare professionals are broadly supportive, but some important barriers and issues remain. Firstly, a need for training and consistency in practice and protocols has been identified. Secondly, additional ‘pump priming’ resources are needed, but these will generate savings which will more than match expenditure.

Recommendations

We have set out some key recommendations below:

1. Unspecified donation is a relatively safe, acceptable practice which should be encouraged.
2. The findings of the BOUnD study should be disseminated to all transplant centres.
3. A training and information programme for transplant centres should be initiated.
4. A consistent approach across centres, and a policy statement regarding age limits, is essential.
5. Consideration should be given to support for those donors who cannot proceed to donation.
6. Further resource, particularly in the form of transplant co-ordinators, is necessary and economically justifiable.

Real-world impact

The effect of unspecified donation in the UK on living donation has been profound, particularly as the majority of these donors are now used to prime ‘chains’ of transplants, via the NKSS, which allows those who are difficult to transplant to receive an organ. One unspecified donation can lead to several transplants (In 2018–9, a total of 64 UKDs primed chains in the UK KSS, resulting in 134 transplants). This study has shown that unspecified donation is justified and should be supported, and has highlighted a number of potential barriers which, if overcome, would lead to an increase in the number of unspecified donation, and thus to a substantial increase in the number of transplants. In the early 2000s, NHSBT offered ‘pump priming’ resource to transplant centres in order to increase the rate of specified living donation, with great success, and a similar initiative now would likely have a profound effect. Healthcare professionals can be

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Mamode N, Norton S, McCrone P, Chilcot J, Draper H, Gogalniceanu P, *et al.* Barriers to and outcomes of unspecified kidney donation in the UK: BOUnD, a mixed-methods study.
Health Soc Care Deliv Res 2025;**13**:20. https://doi.org/10.3310/RTEW9328

reassured that the practice is justified and will be helped by further training and information.

The UK is one of only a few countries where unspecified donation is practised, and the study is likely to provide much-needed evidence for national programmes considering the introduction of such donations.

Future research

No data exist regarding long-term psychosocial outcomes after UKD, and follow-up of donors at 3–5 years after donation would be a valuable study. Our qualitative studies have suggested that further work should be carried out to determine how donors who withdraw, or are withdrawn by the healthcare team, can be supported and to explore the sometimes-difficult interactions they have with their families. Withdrawal is likely to have different implications for those donating to a specified recipient, especially if that individual has no other potential donors. This is a relatively under-researched area in the field of living donation, and this justifies further studies.

While this study provides reassurance that UKDs do not have inferior outcomes to SKDs, it does raise some interesting questions regarding living donation more broadly. It is not unreasonable to expect SKDs to benefit more from donation, given that they are a direct witness to the positive impact it has on their recipient. This study, however, has shown that outcomes are equivalent, which implies that either little is gained by witnessing the outcome or that UKDs benefit equally by anticipating what the outcome may have been. It is also possible that for SKDs, the positives associated with witnessing the positive outcomes are offset by longer terms stresses or anxieties associated with living with a loved one with a chronic health condition. Further study into this area is justified to ascertain how behavioural change interventions may provide a way of helping donors manage these emotions in the long term.

Conclusion

In summary, we believe the BOUnD study has achieved its aims. We have determined that healthcare professionals are broadly supportive, but that there are areas which need to be addressed, such as age limits, mental health assessments and adequate time and training. We have shown that the physical and psychosocial outcomes of unspecified donors are acceptable, with low levels of regret, and potential economic benefits to the NHS.

Additional information

CRediT contribution statement

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

Professionals Study (RQ1)-HRA approval (170483). Participant Cohort Study (RQ2): ethical approval from South Central-Berkshire B Research Ethics Committee (15/SC/0637). Approval was granted on 27 November 2015.

Information governance statement

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Dissemination

A copy of this synopsis and associated publications will be sent to NHSBT, the National Kidney Federation (the UK patients' association), the British Transplant Society, Give a Kidney (the UK charity promoting unspecified donation) and Kidney Care UK (the main UK kidney disease charity).

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/RTEW9328.

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Heather Draper has declared the following interests:

- AHRC (UKRI Ideas to Address COVID-19) (Co-applicant)
- UK Spine (Research England's Connecting Capability Fund) (Principal Applicant)
- CIFAR (Principal Applicant)
- Birmingham Women's and Children's NHS Foundation Trust [Ethics Advisory Group member (unpaid)]
- Defense Medical Services [Ethics Committee member (unpaid)]

Jan Shorrock has declared the following interests:

- £300 received for attending meetings in early stages of project, plus travel costs covered
- employed as freelance Executive Officer by Give a Kidney charity.

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This synopsis was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Trial registration

This trial is registered as Current Controlled Trials ISRCTN23895878.

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Award publications

This synopsis provided an overview of the research award Unspecified living kidney donation in the UK: barriers to implementation and delivery. Other articles published as part of this thread are:

Gare R, Gogalniceanu P, Maple H, Burnapp L, Clarke A, Williams L, *et al*. Understanding barriers and outcomes of unspecified (non-directed altruistic) kidney donation from both professional's and patient's perspectives: research protocol for a national multicentre mixed-methods prospective cohort study. *BMJ Open* 2017;**7**:e015971. https://doi.org/10.1136/bmjopen-2017-015971

Maple H, Draper H, Gogalniceanu P, Burnapp L, Chilcot J, Mamode N. Donating a kidney to a stranger: a review of the benefits and controversies of unspecified kidney donation. *Ann Surg* 2020 Jul;**272**:45–7. https://doi.org/10.1097/SLA.0000000000003855

Maple H, Gogalniceanu P, Gare R, Burnapp L, Draper H, Chilcot J, *et al*. Donating a kidney to a stranger: are healthcare professionals facilitating the journey? Results from the BOUnD study. *Transpl Int* 2023 May 30;**36**:11257. https://doi.org/10.3389/ti.2023.11257

Zuchowski M, Mamode N, Draper H, Gogalniceanu P, Norton S, Chilcot J, *et al*. Exploring staff attitudes towards unspecified kidney donors in the United Kingdom: results from the BOUnD study. *Transpl Int* 2023;**36**:11258. https://doi.org/10.3389/ti.2023.11258

Maple H, Gogalniceanu P, Zuchowski M, Draper H, Burnapp L, McCrone P, *et al*. Outcomes and motivations in unspecified kidney donation: results from a UK prospective study. *Am J Transplant* 2025:S1600-6135(25)00150–9. https://doi.org/10.1016/j.ajt.2025.03.021

Zuchowski M, Mamode N, Draper H, Gogalniceanu P, Norton S, Chilcot J, *et al*. Experiences of completed and withdrawn unspecified kidney donor candidates in the United Kingdom: an inductive thematic analysis from the BOUnD study. *Br J Health Psychol* 2021;**26**:958–76. https://doi.org/10.1111/bjhp.12514

For more information about this research, please view the award page www.fundingawards.nihr.ac.uk/award/13/54/54.

Additional outputs

Morris T, Maple H, Norton S, Chilcot J, Burnapp L, Draper H, *et al*. Challenges and opportunities in the supply of living kidney donation in the UK National Health Service: an economic perspective. *Transplantation* 2022;**106**:2137–42. https://doi.org/10.1097/TP.0000000000004176

European Society of Transplantation 2021, Milan – presentation.

What happens to unspecified kidney donor candidates who cannot proceed to donate: an inductive thematic analysis from the BOUnD study – brief oral presentation.

Analysing the financial costs and benefits of unspecified kidney donation in the UK: results from the BOUnD study – latebreaking e-poster.

Comparing physical and psychosocial outcomes in unspecified versus specified kidney donors at 3 months after donation: results from the BOUnD study – late-breaking e-poster.

Donating a kidney to a stranger: are healthcare professionals facilitating the journey? results from the BOUnD study – focus group – hot issues in living kidney donation.

British Transplant Society Annual Congress Belfast 2022.

Do unspecified kidney donors in the UK differ from specified donors? – results from the BOUnD study.

Oral presentation: winner of the prestigious Medawar Prize.

British Transplant Society Annual Congress 2021 (online).

'If you want to help people, go volunteer at a soup kitchen': exploring staff attitudes towards unspecified kidney donors in the UK – oral presentation.

British Transplant Society Annual Congress Harrogate 2019.

Unspecified (altruistic) kidney donors take significantly longer to donate than specified donors – results from the BOUnD study – oral presentation.

About this synopsis

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List of abbreviations

BOUND	Barriers and Outcomes in Unspecified Donation
CSRI	Client Service Receipt Inventory
ELPAT	Ethical, Legal and Psychosocial Aspects of Transplantation
FG	focus group
FGD	focus group donated
FGND	focus group not donated
GP	general practitioner
KSS	kidney sharing scheme
NHSBT	NHS Blood and Transplant
NKSS	National Kidney Sharing Scheme
QALY	quality-adjusted life-year
SKD	specified kidney donor
UKD	unspecified kidney donor

List of supplementary material

Report Supplementary Material 1
Questionnaire for professionals' study (RQ1)

Details of questionnaire development (RQ2)

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/RTEW9328).

Supplementary material has been provided by the authors to support the report, and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

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Appendix 1 Withdrawn versus completed donors

Aims and objectives

This analysis, using the same methodology and data set described in RA5, relates to BOUnD RQ1 ‘Whether variation in practice and attitudes across the UK is unnecessarily preventing some unspecified kidney donation’. The specific objectives are to:

1. estimate rates of (a) donation and (b) withdrawal in potential UKDs, compared with potential SKDs
2. identify individual-level factors associated with (a) donation and (b) withdrawal in potential UKDs
3. identify centre-level factors associated with (a) donation and (b) withdrawal in potential UKDs.

Statistical analysis

Cumulative incidence functions for donation and withdrawal were estimated based on competing-risks regression models, according the Fine and Gray (1999) method.[30] Separate models were estimated for donation with withdrawal as a competing risk, and vice-versa withdrawal with donation as a competing risk. This approach ensures that cumulative incidence rates are not overestimated, as they would be based on the Kaplan–Meier survivor function. In this analysis, individuals are included in the analysis from the recorded time of first contact until they donate or withdraw from the process – either self-withdraw for personal reasons or are withdrawn on medical grounds. Where neither event occurs, individuals are censored either 3 years from their first contact with the centre or on the last day of observation (30 September 2020), whichever is sooner. In addition to right censoring, we account for left truncation due to delayed entry into the study, where individuals are recruited at some point after their first contact with the centre. Where date of first contact was not recorded, this was imputed using the median for the sample. Sensitivity analyses were undertaken to determine variability in the estimates using time from recruitment to donation or withdrawal and also the impact of the COVID-19 pandemic by censoring follow-up on 1 March 2020.

Factors associated with donation and withdrawal were assessed via Cox proportional-hazards regression models, including shared frailty (i.e. random effect) for recruiting centre to allow for different rates of donation and withdrawal between centres. A Cox model was used since shared frailties are not available for competing-risks regression model. This is appropriate given the parameter of interest here is the hazard ratio and not the cumulative incidence function, where only the estimate of the latter is biased for Cox models. Separate models were estimated for each variable of interest adjusting for age and gender. Of interest here are factors association with donation and withdrawal in the potential unspecified donors. For

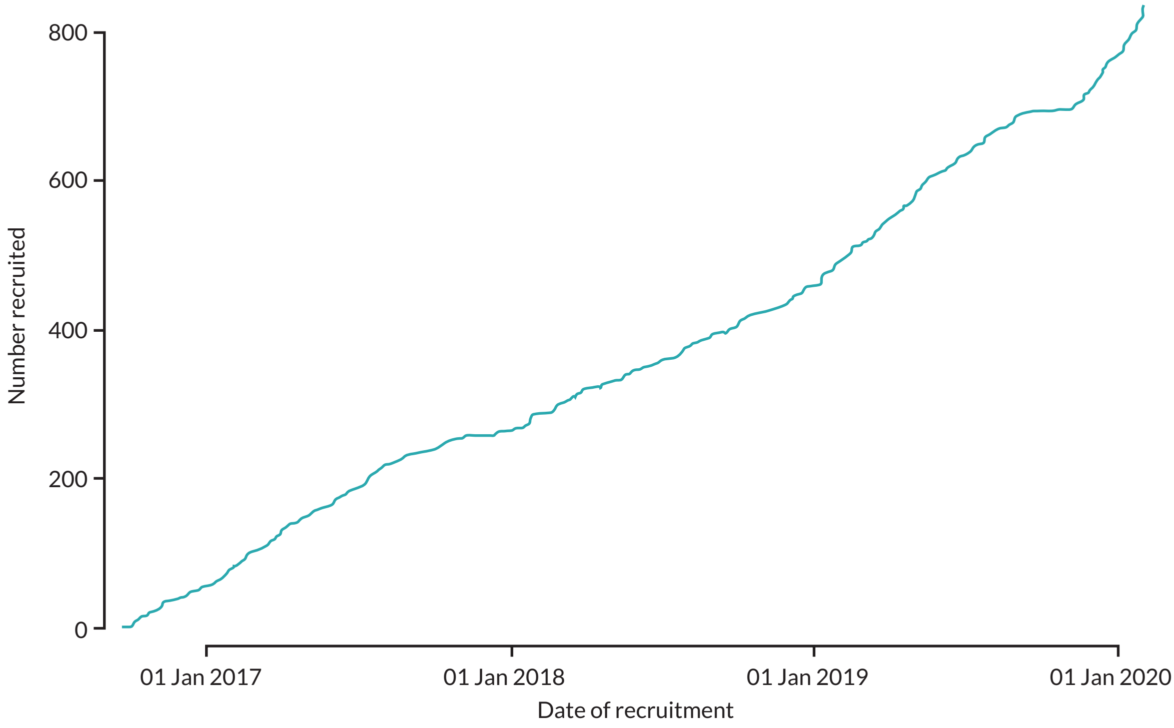


FIGURE 2 Recruitment over time.

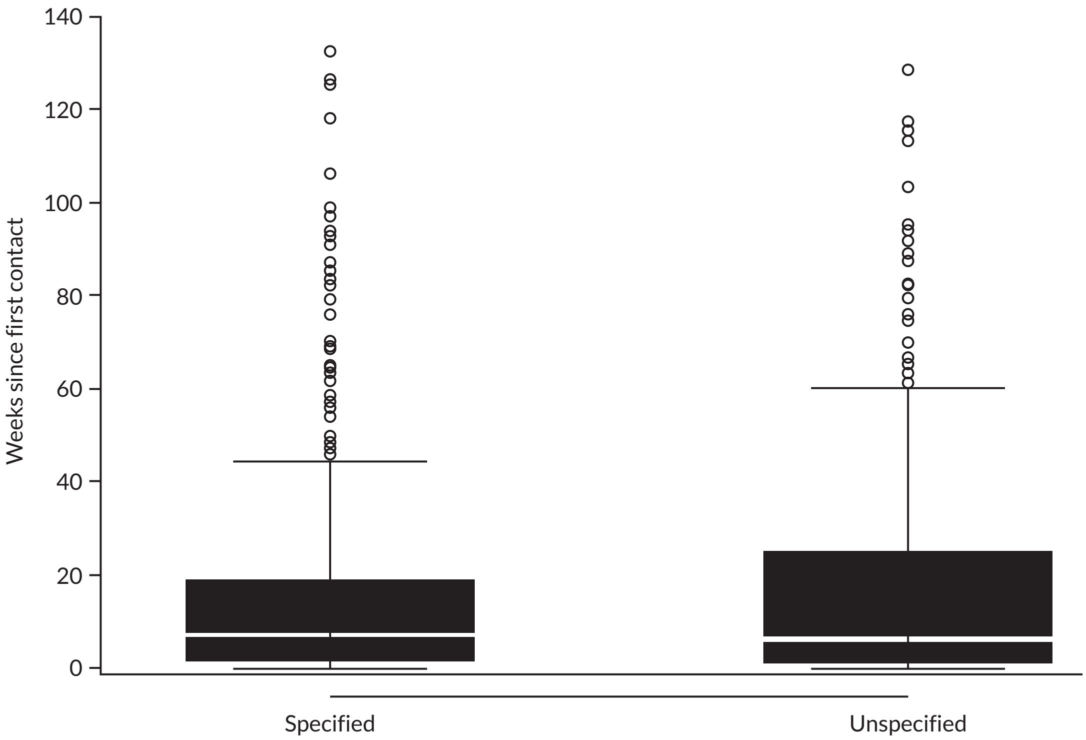


FIGURE 3 Time between first contact with centre and consenting to participate in the study.

completeness, factors associated with donation and withdrawal in the potential specified donors were also estimated. Given a number of people consented but did not complete the baseline questionnaire estimates are provided for the complete case sample and using multiple imputation. Multiple imputation, with 10 imputed data sets, used chained iterations approach and included age, sex, donor type, analysis time and status at 3 years in the imputation model along with baseline variables with missing data.

TABLE 1 Centre-level data

Centre	Farrington classification	Total UKD staffing	Physicians/ surgeons	UKD specific donor co-ordinator	BOUnD recruits	BOUnD SKD donations	BOUnD UKD donations	Percentage capture of UKDs	Percentage UKD volume	UKD support score
Belfast	1	10	7	0	78	31	18	62	9	54.9
Birmingham	1	16	8	1	7	0	0	0	3	48.9
Bristol	1	10	6	0	15	3	5	44	7	54.3
Cambridge	1	7	4	0	37	10	5	42	8	43.5
Cardiff	1	16	11	1	66	6	5	63	6	54.5
Coventry	1	8	4	0	8	4	2	40	5	52.6
Edinburgh	1	14	10	1	44	17	13	39	16	50.1
Glasgow	1	16	10	0	18	1	7	50	7	48.5
Leeds	1	13	9	0	14	1	8	38	10	51.0
Leicester	1	7	6	0	9	5	0	0	2	52.0
Liverpool	1	7	5	0	7	0	5	42	8	50.0
London, Guy’s	1	22	13	1	156	34	29	74	9	52.7
London, Hammersmith	1	12	9	0	45	8	5	63	0	53.5
London, Royal Free	1	8	5	1	15	0	4	100	3	55.3
London, Royal London	1	9	7	0	20	4	0	0	5	50.5
London, St George’s	1	8	6	0	13	0	3	38	5	51.5
Manchester	1	14	11	0	55	21	17	52	9	50.2
Newcastle	1	5	3	0	33	14	3	0	6	50.4
Nottingham	1	8	6	0	18	1	2	22	13	57.1
Oxford	1	11	7	0	51	14	5	24	10	56.2
Plymouth	1	16	14	0	19	4	13	68	20	54.6
Portsmouth	1	13	9	0	81	20	17	62	22	51.9
Sheffield	1	8	5	0	28	6	3	38	10	54.5
Sum/Mean		258	175	5	837	204	169	42	8	52.1

Results

Sample characteristics

In total, 837 potential donors (496 specified, 341 unspecified) were recruited from 23 transplant centres (mean = 36.4 per-centre) between September 2016 and January 2020 (*Table 1*). The median date from first contact with the centre to consenting to participate in the study was 48 days overall [interquartile range (IQR) 10–146], and slightly shorter for potential unspecified compared to potential specified donors (median 41.5 days vs. 50 days), *Appendix 1*, *Figure 2*. The characteristics of each recruiting centre, number of recruits and numbers proceeding to donation during the period of observation are shown in *Appendix 1*, *Table 1* and *Appendix 1*, *Figure 3*.

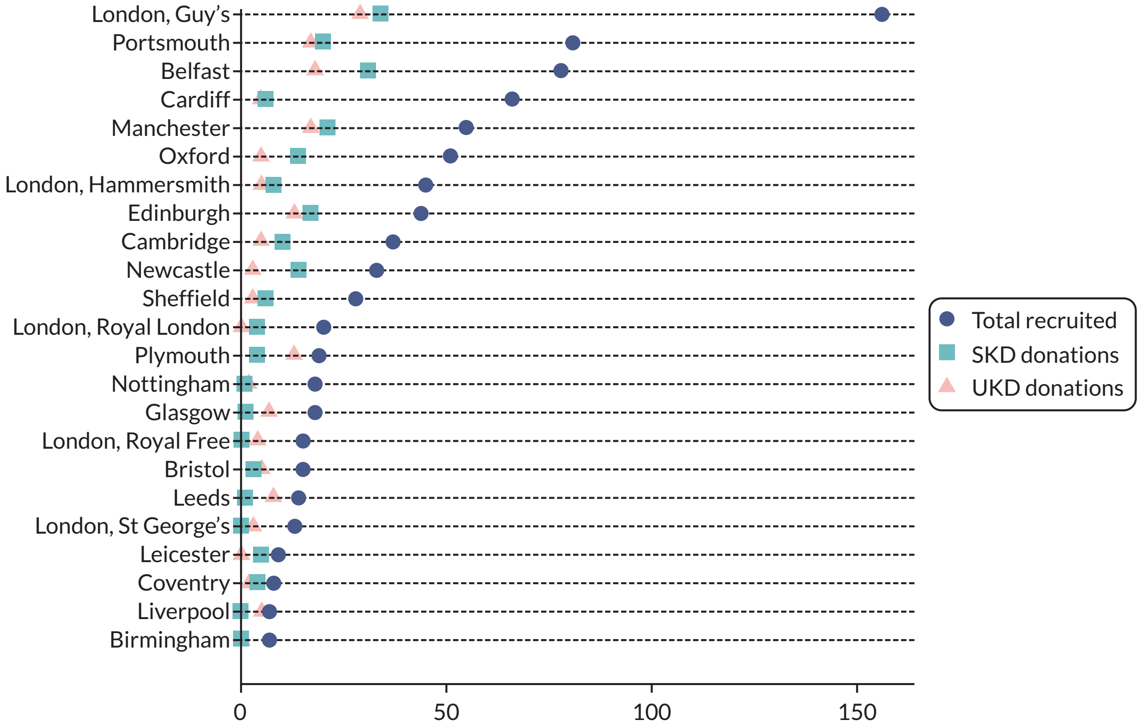


FIGURE 4 Recruits and donations per centre.

Of the 837 potential donors, 688 (82.2%) returned completed baseline questionnaires. Demographic characteristics of the sample by donor type and baseline survey completion are shown in *Appendix 1*, *Tables 2* and *3*. Potential unspecified donors were less likely to be females, have higher levels of education, and better mental health when compared to potential specified donors. Potential unspecified donors were also more likely to return the baseline questionnaire compared to potential specified donors. Potential donors from ethnic minorities were less likely to complete the baseline questionnaire.

Cumulative incidence of donation and withdrawal

Of the 837 people recruited, 817 (97.6%) were included in the time-to-event analysis sample. The 20 excluded participants (13 specified, 7 unspecified) were excluded due to unknown date of first contact (*n* = 3), date of first contact more than 3 years prior to recruitment (*n* = 11), and already being withdrawn from the process at the time of completing the baseline questionnaire (*n* = 6).

With the analysis time censored at 3 years from first contact with the centre, there were a total of 365 donations (specified 200, unspecified 165) and 185 withdrawals (specified 101, unspecified 84) across a total of 743.9 person-years of follow-up. Cumulative incidence functions for donation and withdrawal for specified and unspecified donors are presented in *Appendix 1*, *Figure 5*. By 6 months, cumulative incidence of donation was higher for specified donors compared to unspecified donors (36.9% vs. 28.3%) and cumulative incidence of withdrawal lower (11.0% vs. 15.1%). However, cumulative incidence rates at 3 years were approximately equal (donation: 67.2% vs. 66.7%; withdrawal: 29.6% vs. 28.3%). Respectively, age–sex-adjusted hazard ratios for donation and withdrawal for unspecified compared to specified donors were 0.97 (95% CI 0.67 to 1.40) and 1.12 (95% CI 0.75 to 1.67).

There was considerable variability in cumulative incidence rates of donation and withdrawal across centres. *Appendix 1*, *Figures 6* and *7* plot rates for the 11 centres recruiting at least 20 potential donors overall.

Reasons for withdrawal were not recorded for many patients, which limits the ability to draw inferences (see *Appendix 1*, *Table 4*). However, there was an indication of increased withdrawal for medical reasons in the group of potential unspecified donors.

Factors associated with proceeding to donation and withdrawal

Cox regression models with shared frailty for recruiting centre were estimated to assess the individual- and centre-level factors associated with proceeding to

TABLE 2 Demographic variables and patient-reported outcome by donor type

		Specified	Unspecified	
		N = 496	N = 341	p-value
Age at the time of donation	Mean (SD)	50.6 (12.5)	50.1 (15.2)	0.720
Female	n (%)	297 (59.9%)	166 (48.8%)	0.002
Ethnicity				
White	n (%)	355 (92.0%)	296 (94.3%)	0.320
Asian	n (%)	12 (3.1%)	4 (1.3%)	
Black	n (%)	5 (1.3%)	1 (0.3%)	
Mixed	n (%)	8 (2.1%)	7 (2.2%)	
Other/unknown	n (%)	6 (1.6%)	6 (1.9%)	
Education				
None/school level	n (%)	113 (29.3%)	55 (17.5%)	< 0.001
Further education	n (%)	117 (30.3%)	83 (26.4%)	
Higher education	n (%)	156 (40.4%)	176 (56.1%)	
Weeks since first contact	Median (IQR)	7.3 (1.7–20.4)	6.3 (1.0–25.4)	0.68
SF-12 physical summary	Mean (SD)	54.8 (6.0)	55.1 (6.1)	0.640
SF-12 mental summary	Mean (SD)	53.0 (7.3)	53.0 (7.9)	0.970
PHQ-9 depression	Mean (SD)	1.3 (2.3)	1.2 (2.3)	0.500
GAD-7 anxiety	Mean (SD)	1.8 (3.0)	1.0 (1.8)	< 0.001
Rosenberg self-esteem	Mean (SD)	33.3 (4.6)	32.6 (4.8)	0.054
Diener life satisfaction	Mean (SD)	26.8 (5.4)	25.9 (6.1)	0.037
Diener flourishing	Mean (SD)	47.6 (6.0)	46.5 (6.5)	0.028
MSPSS social support	Mean (SD)	66.8 (19.4)	65.8 (16.2)	0.440

GAD-7, General Anxiety Disorder-7; MSPSS, Multidimensional Scale of Perceived Social Support; PHQ-9, Patient Health Questionnaire-9 items; SD, standard deviation; SF-12, Short Form questionnaire-12 items.

donation or withdrawal. Separate models were estimated for each outcome and stratified by potential unspecified and specified donors. Age–sex-adjusted hazard ratios for the complete-case analysis, including those completing the baseline questionnaire, are presented in *Appendix 1*, *Figure 8* and form the multiply-imputed analysis in *Appendix 1*, *Figure 9*.

For the potential unspecified donors, older age and higher education were the only two individual-level factors significantly associated with proceeding to donation. Neither of which effect was observed in the potential specified donors. In the potential specified donors, mental health variables tended to be significantly related to a greater likelihood of donation.

The only individual-level factors related to withdrawal in the potential unspecified donors were mental health variables. The effects were in the same direction for the potential specified donors, but none of the variables were significant.

Of the centre-level factors, the total number of unspecified donations at the centre during the period of recruitment was the only variable associated with donation and was significant for both the potential specified and unspecified donors. Total number of unspecified donations variable was also negatively related to the number of withdrawals for potential unspecified donors. Higher numbers of unspecified donor co-ordinators, total number of transplant staff, and higher average support score from

TABLE 3 Demographic variables by missing data status

		Completed baseline questionnaire	**Did not complete baseline questionnaire**	
		***N* = 688**	***N* = 149**	***p*-value**
Age at the time of donation	Mean (SD)	50.4 (13.8)	47.9 (13.5)	0.520
Female	*n* (%)	380 (55.2%)	83 (56.1%)	0.850
Ethnicity				
White	*n* (%)	640 (93.3%)	11 (78.6%)	0.017
Asian	*n* (%)	15 (2.2%)	1 (7.1%)	
Black	*n* (%)	6 (0.9%)	0 (0.0%)	
Mixed	*n* (%)	13 (1.9%)	2 (14.3%)	
Other/unknown	*n* (%)	12 (1.7%)	0 (0.0%)	
Education				
None/school level	*n* (%)	164 (23.9%)	4 (28.6%)	0.190
Further education	*n* (%)	199 (29.0%)	1 (7.1%)	
Higher education	*n* (%)	323 (47.1%)	9 (64.3%)	
Weeks since first contact	Median (IQR)	9.6 (1.7–24.1)	6.4 (1.3–21.7)	0.170
Donor type				
Specified	*n* (%)	379 (55.1%)	117 (78.5%)	< 0.001
Unspecified	*n* (%)	309 (44.9%)	32 (21.5%)	

SD, standard deviation.

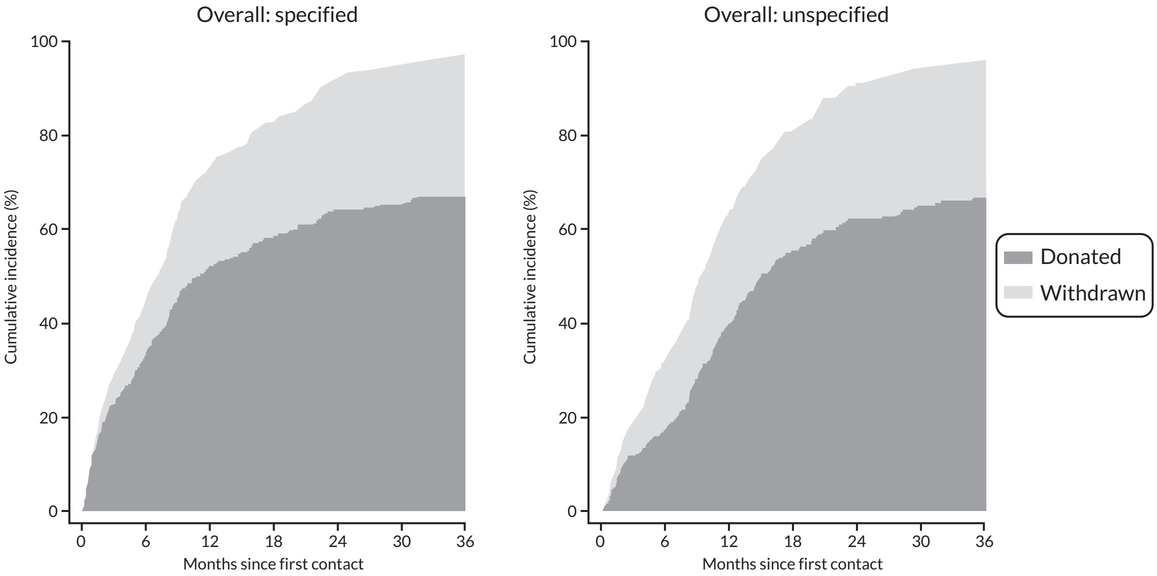


FIGURE 5 Cumulative incidence of donation and withdrawal.

TABLE 4 Reasons for withdrawal

	Specified ***N* = 101**	**Unspecified** ***N* = 84**	***p*-value**
Reason for withdrawal			
Self	27 (26.7%)	14 (16.7%)	< 0.001
Medical	17 (16.8%)	36 (42.9%)	
Unknown	57 (56.4%)	34 (40.5%)	

the centre survey were also related to lower rates of withdrawal (see *Appendix 1*, *Figure 10*).

Sensitivity analysis

Sensitivity analysis was undertaken using time since recruitment to donation or withdrawal as the metric for the survival analysis (see *Appendix 1*, *Figure 11*). As would be anticipated, the cumulative incidence rates were reduced; such that at 3 years, cumulative incidence for the specified and unspecified donors, respectively, were 49.1% and 52.0% for donation and 28.2% and 27.3% for withdrawal. The general inference regarding the difference remained the same when compared to the analysis based on time since first contact. Respectively, age–sex-adjusted hazard ratios for donation and withdrawal for unspecified donors compared to specified donors were 0.99 (95% CI 0.72 to 1.36) and 1.10 (95% CI 0.75 to 1.62).

Further sensitivity analysis censored follow-up on 1 March 2020, rather than 30 September 2020. This reduced the total amount of follow-up from 743.9 person-years to 664.4 person-years. During which time, there were 358 donations and 166 withdrawals. Although direct comparisons are difficult, given recruitment was complete before the pandemic, overall crude incidence rates for donation for the total sample was 55.3 per 100 person-years pre pandemic and reduced to 16.4 per 100 person-years during the pandemic. The crude rate of withdrawal was unchanged from 23.8 per 100 person-years pre pandemic to 23.9 per 100 person-years during the pandemic (see *Appendix 1*, *Figure 12*).

Conclusions

We found a significant variation in withdrawal rates across centres. Those dealing with higher numbers of UKDs, and those with more staff overall and, in particular, more co-ordinators for UKDs, had lower rates of withdrawal of UKDs. Interestingly, the high-volume UKD centres had lower rates of withdrawal of both UKDs and SKDs.

The rate of withdrawal in SKDs was lower than UKDs during early follow-up, but this difference had disappeared by 3 years. This could be due to slower workup for UKDs, more early medical withdrawals in that group, or because some SKDs are expedited to pre-emptively transplant the recipient, although a significant number of withdrawals had no stated reason. Withdrawal rates were lower in older, more educated UKDs, and higher in the anxious and depressed. We found no evidence of a change in withdrawal rates during the pandemic. Unsurprisingly, UKDs had a shorter time from first contact to consent for the study, which likely represents enthusiasm for donation.

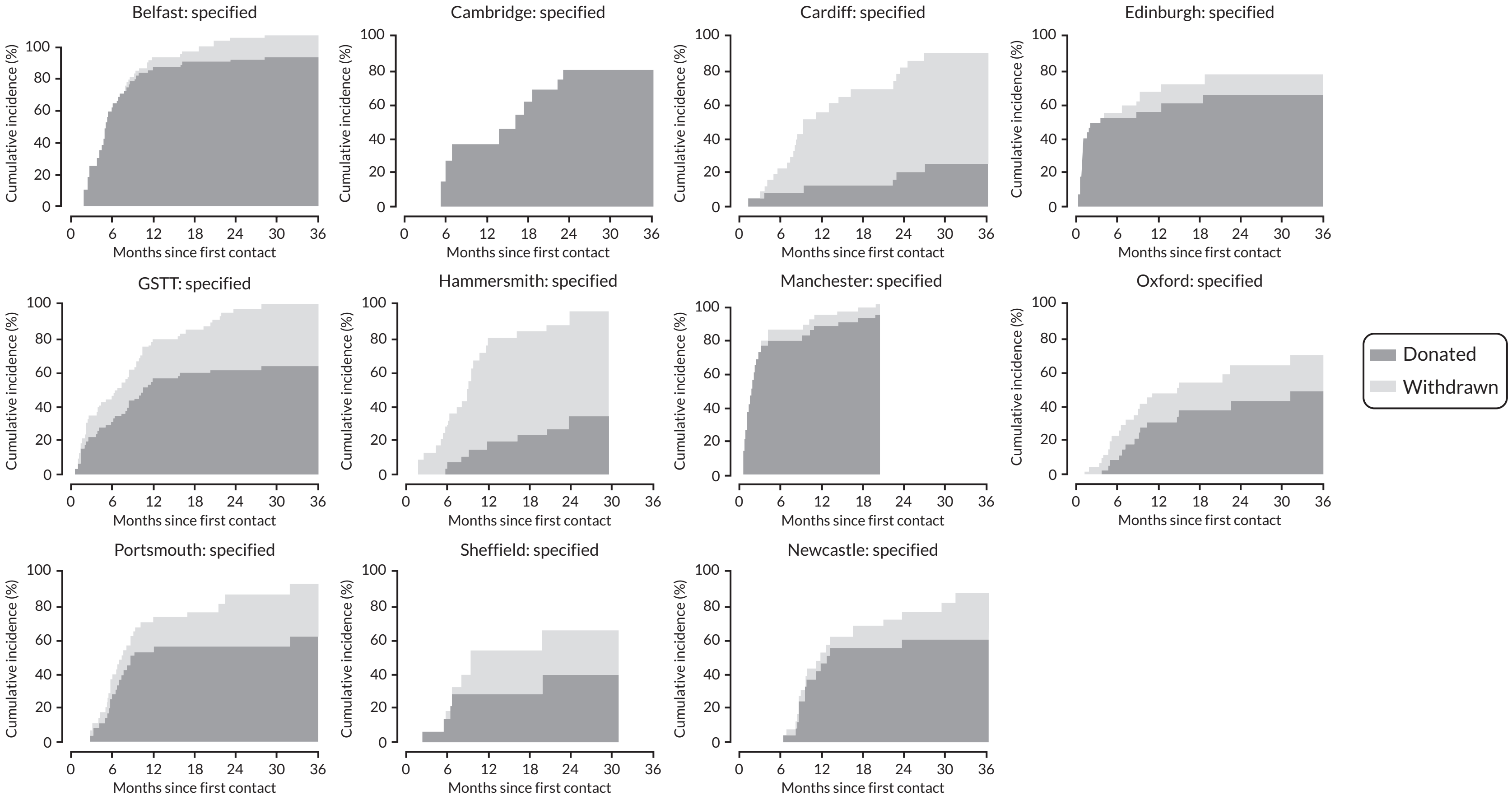


FIGURE 6 Cumulative incidence of donation and withdrawal for specified donors by centre.

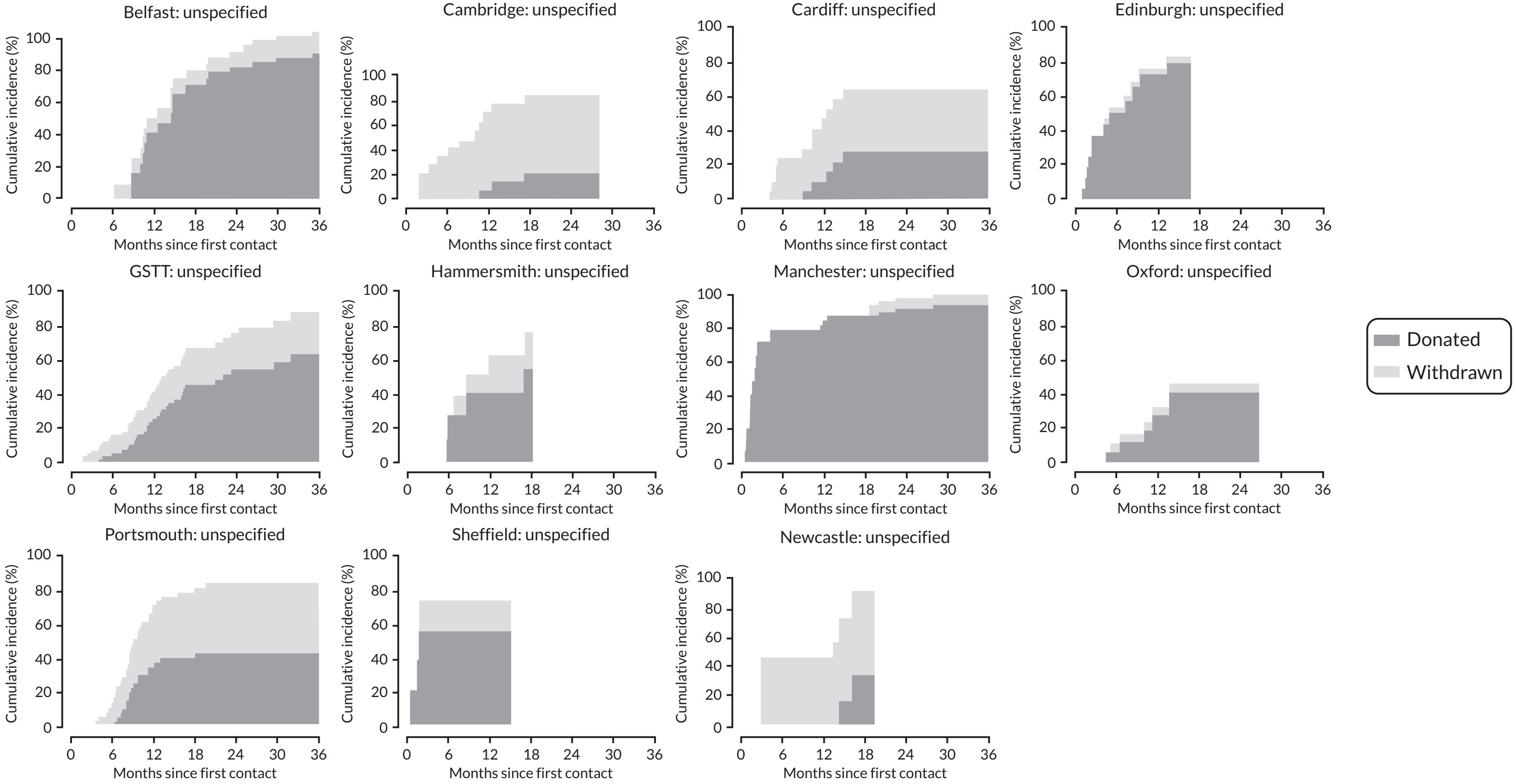


FIGURE 7 Cumulative incidence of donation and withdrawal for unspecified donors by centre.

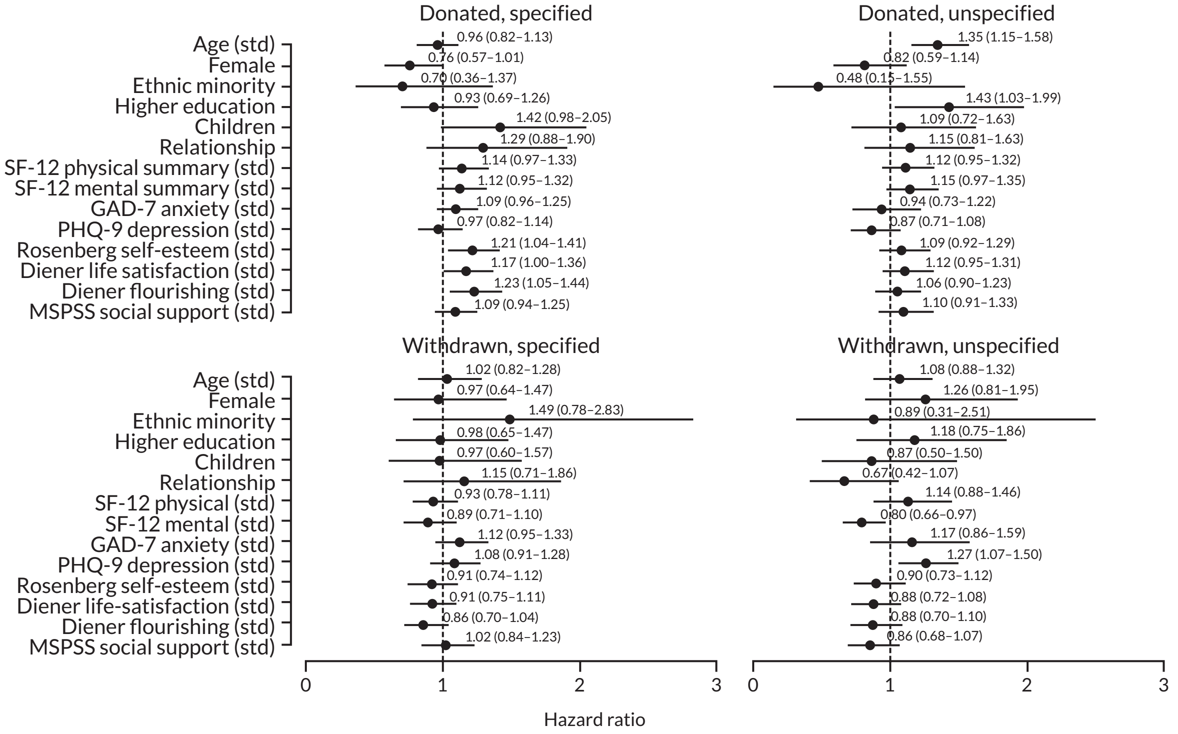


FIGURE 8 Age–sex-adjusted individual-level predictors of donation and withdrawal (complete-case analysis, n_{max} = 688). Std indicates that the hazard ratio refers to a 1 standard deviation change in the variable.

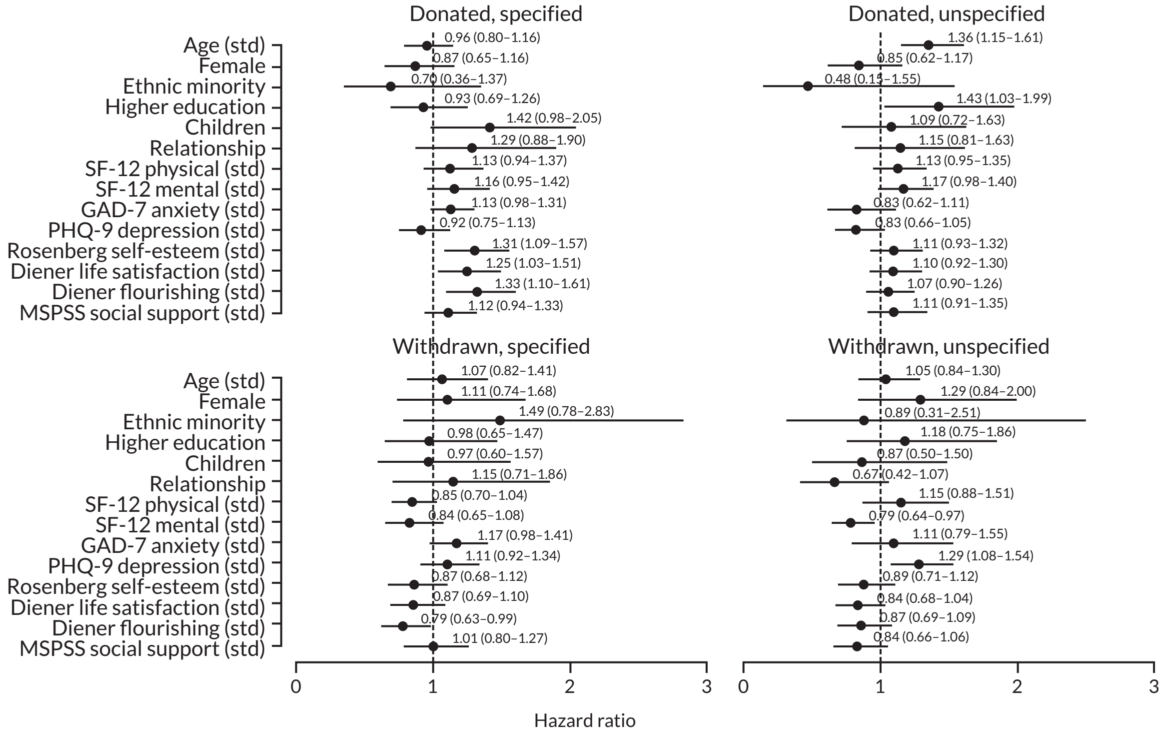


FIGURE 9 Age–sex-adjusted individual-level predictors of donation and withdrawal (multiply-imputed analysis, n = 817). Std indicates that the hazard ratio refers to a 1 standard deviation change in the variable.

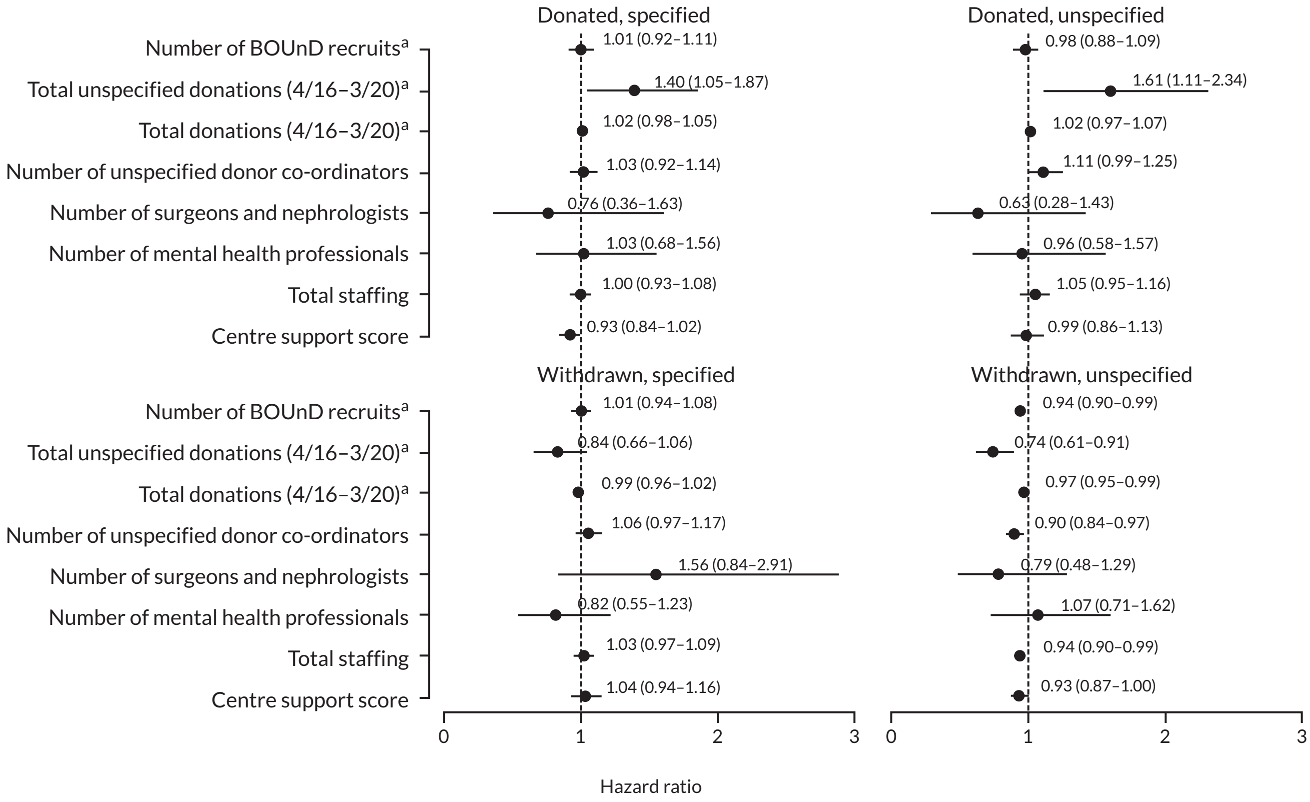


FIGURE 10 Case-mix adjusted centre-level predictors of donation and withdrawal (n = 817). a, Hazard ratio is per 10.

This synopsis should be referenced as follows:
Mamode N, Norton S, McCrone P, Chilcot J, Draper H, Gogalniceanu P, *et al.* Barriers to and outcomes of unspecified kidney donation in the UK: BOUnD, a mixed-methods study. *Health Soc Care Deliv Res* 2025;**13**:20. https://doi.org/10.3310/RTEW9328

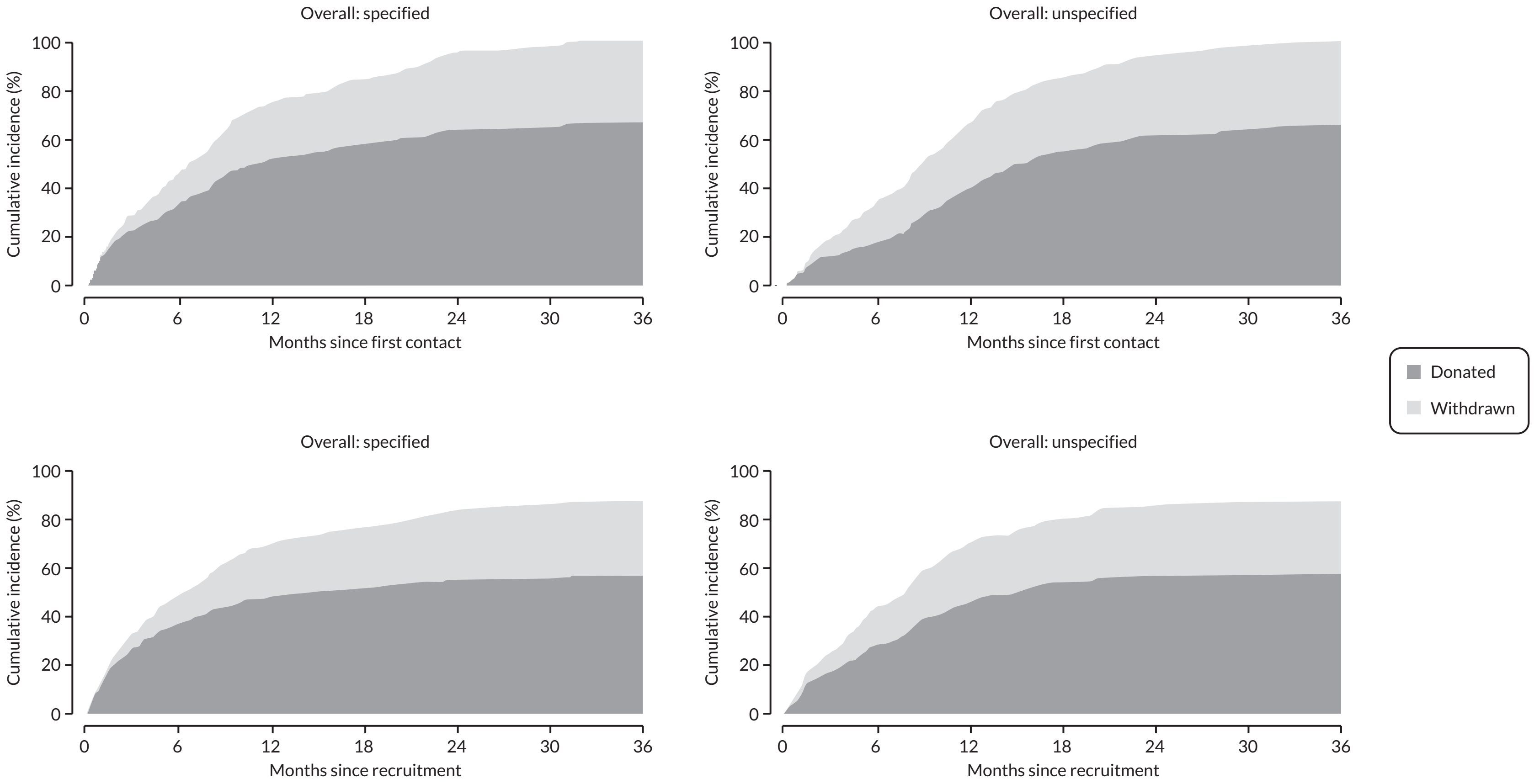


FIGURE 11 Cumulative incidence of donation and withdrawal comparing time since first contact (top row, identical to *Appendix 1*, *Figure 5*) and time since recruitment (bottom row).

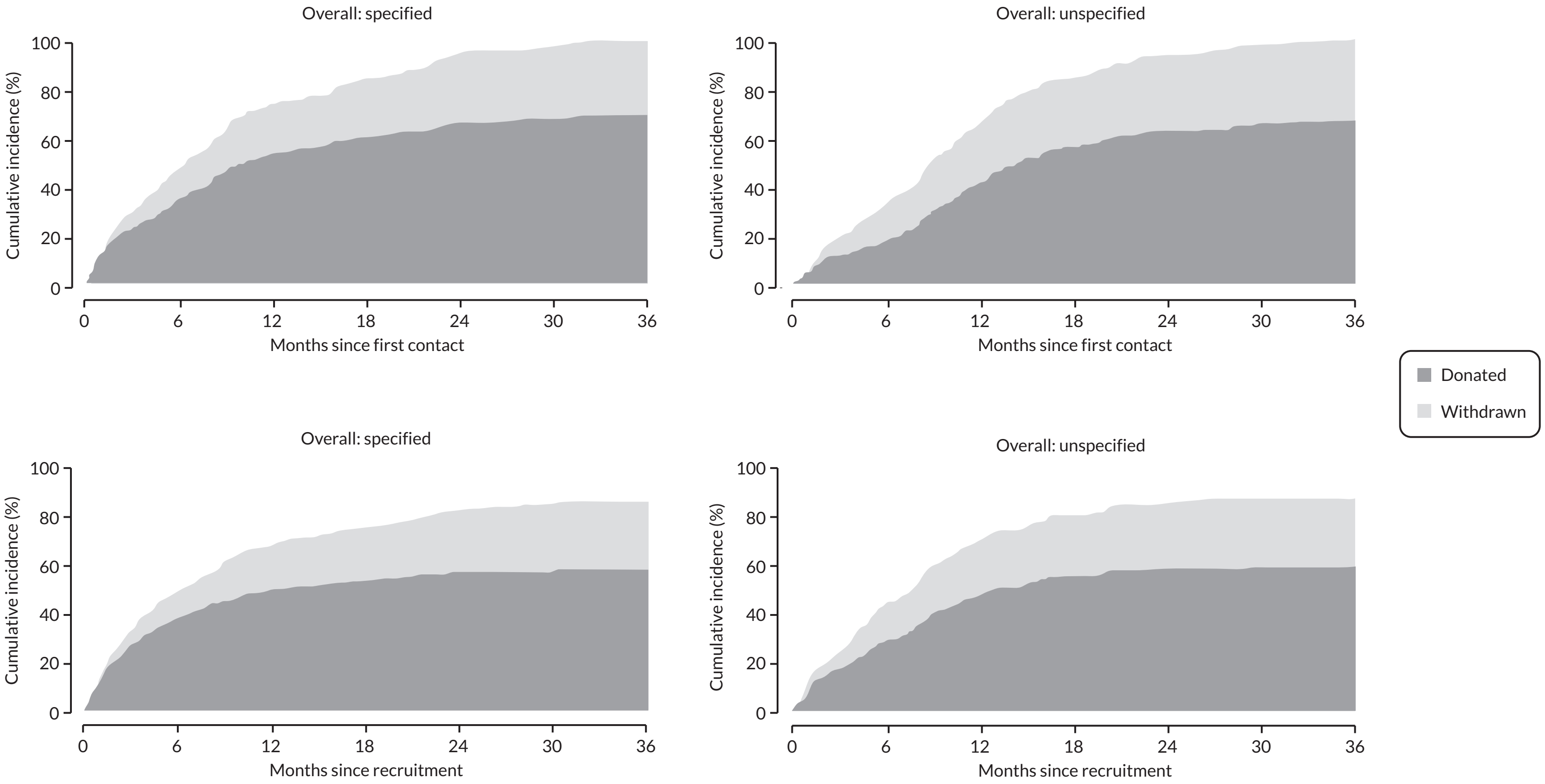


FIGURE 12 Cumulative incidence of donation and withdrawal, excluding pandemic period (i.e. censored at 1 March 2020).

Appendix 2

Focus group analysis of donated and withdrawn unspecified kidney donation candidates

Two focus groups (FGs) were held at a large urban teaching hospital. One group comprised five individuals who had donated as part of the UKD scheme [focus group donated (FGD)]. The other comprised individuals who had been withdrawn by the transplant team or who had chosen to withdraw [focus group not donated (FGND)]. Four participants who had been withdrawn by the team, and one who had made a personal decision to withdraw. Both groups comprised participants who were broadly similar in age range, gender and family demographics (see *Appendix 2*, *Table 5*).

Researchers accessed patient records in high-volume transplant centres to establish eligibility to participate and recruit prospective participants. Participation criteria included individuals who had presented to the transplant centre as a potential UKD and had either donated or not donated. Formal written consent was obtained from each participant.

Themes relevant to the research question were identified from the existing literature, including work conducted by the research team,[4,8] and incorporated into the FG schedules. These differed for each group in respect to the different pathways each group had taken. Focus groups were conducted in December 2015 and January 2016 and were facilitated by two researchers (LW, a postdoctoral psychology researcher; and AC, a clinical psychologist). The duration of each group was 90 minutes.

Analytic procedure

Focus groups were audio-recorded, transcribed verbatim and anonymised. Data immersion was facilitated by iterative reading of the data transcripts on at least three occasions. This was performed in conjunction with the study of the original audio recordings. Data management and coding analysis was performed using the QSR NVivo 11 (QSR International, Warrington, UK) software package. Extracts of the transcripts were coded into one or more initial categories derived from the themes contained within the FG schedules. Categories were further refined following the method of framework analysis to elucidate final themes[29,30]. Thematic condensation resulted in four final themes which best captured the contrast between the completed and withdrawn groups.

Analysis

The four principal themes resulting from the analysis. These addressed the following:

1. relationships with the recipient
2. role of the family
3. experiences of transplant professionals
4. perspectives on publicity.

Thematic description and interpretation are provided in the following section. Illustrative quotes are provided, with those who had donated denoted by the initials 'FGD', followed by a letter representing the individual participant.

TABLE 5 Focus group participant demographics

Identifier	Sex	Age	Relationship status	Children	Withdrawal
FGC/a	F	60	Unknown	Yes	
FGC/b	M	69	Unknown	Yes	
FGC/c	M	71	Married	Yes	
FGC/d	M	30	Partner	No	
FGC/e	F	60	Unknown	No	
FGW/a	M	40	Unknown	No	Medical
FGW/b	F	66	Married	Yes	Medical
FGW/c	M	73	Married	Yes	Personal
FGW/d	M	47	Divorced	No	Medical
FGW/e	F	53	Married	Yes	Medical

Those who did not donate are similarly identified with the initials 'FGND'.

Theme 1: Relationships with recipients

Acceptance of the outcomes of donation, including the risk of an unsuccessful transplant, featured strongly in the group who had donated. Participants tended to characterise the kidney as an unconditional gift, donated without expectation of a positive outcome or gratitude from the recipient: 'I give it to you to do what you like with it (FGD/b)'. This suggests an underlying confidence in the decision to donate, facilitated by expectation management and detachment from responsibility towards the recipient upon removal of the kidney.

It was apparent that anonymity had great significance in enabling completed participants to accept the outcomes of donation: 'the anonymity of it means that you're freed from baggage of feeling like you're responsible for somebody' *(FGD/e)*. However, participants who had been contacted by their recipient following donation described this as a psychologically beneficial experience: 'I did receive an anonymous letter and it was touching' *(FGD/e)*. Anonymity was constructed as a double-edged sword, protecting participants from the recipient's pain if the donation fails but separating them from the gratification of having changed someone's life when it succeeds.

Participants in the non-donating group also tended to value anonymity as a means of protecting themselves from the outcomes of donation. However, discussion of outcomes was marked by fear rather than acceptance: 'if it didn't work it would be terrible' *(FGND/c)*. There was an impression that withdrawal from the process carried with it an unfinished sense of responsibility towards the recipient: 'you can imagine people backing out at the eleventh hour, it's really frightening (FGND/c)'. This contrasts with the completed group who considered the fate of the recipient to be out of their hands.

Underlying the differing experiences of completed and withdrawn participants was the notion of completeness. It is possible that participants who had donated emphasised acceptance of the outcomes of their donation in order to bring closure to their experience of UKD in the absence of recipient contact. In the non-donating group, participants' experience of UKD was necessarily incomplete. Consequently, they constructed downward counterfactual scenarios. Counterfactual thinking is when individuals reflect upon experiences or life events and consider how things may have turned out differently under somewhat different circumstances.[31] Downward counterfactual thinking is when individuals project negative consequences of their actions, and this was seen within the non-donating group who projected negative consequences for the recipient, had their donation gone ahead. Speculatively, we suggest that counterfactual reasoning was a psychological mechanism for coping with the knowledge of withdrawal and a sense of 'unfinished business'.

Theme 2: Role of the family

Participants in donated group often demonstrated empathy towards members of their family, regarding them as being as closely involved in the donation as themselves: *'the people who are taking the biggest risk are the people who will be here if the worst happens' (FGD/d)*. This was not present within the non-donating group, in which family were largely perceived as a barrier to donation. FGND/c cited the strength of his family's resistance as the reason he self-withdrew: 'I just listened more to my wife and I went "nah, this is gonna be in the too hard basket"'. Family resistance was foregrounded as a barrier to donation by several other withdrawn participants, despite the fact that the ultimate reason for their withdrawal was medical and made by the transplant team.

Consistent with these findings, most participants in the non-donating group characterised informing the family of their intention to donate negatively: 'at some point you realise you just have to talk to them but it's not a nice process' *(FGND/a)*. Subsequently, they often spoke of withholding information in anticipation of a negative response: 'I didn't tell my family because I think that there would be pressure coming from them not to do it' *(FGND/c)*.

The role of the family in both groups was underpinned by the psychosocial dynamic of responsibility. Through the expression of empathy, participants in the donated group indicated responsibility for their families' wellbeing and an understanding of how it was affected by the decisions they make. Although the majority of participants in the non-donating group withheld their decision to donate from their families, there was implicit acknowledgement that it is normal behaviour to inform the family when making serious decisions. For example, FGND/b emphasised that her decision to not tell her children was justified because they were adults, implying that their independence from her also gave her greater autonomy: 'I never told my children who were grown up' *(FGND/b)*.

In the non-donating group several participants used counterfactual reasoning to assert that, despite their resistance, their families would not have prevented them donating: 'he wouldn't of blocked it cos it was all your decision, he's just slightly unsure' *(FGND/b)*. This suggests participants felt responsibility to be mutual and that ultimately their families would be obliged to acknowledge that the decision was theirs to make. However, even with a determination to donate in spite of familial objections, participants from both groups acknowledged the importance of involving the family in the decision to donate and suggested that contact between family, transplant staff and other donors could mitigate opposition.

Theme 3: Experiences with transplant professionals

In the donated group participants commonly reported personal and emotional connections with the transplant professionals the encountered: 'they were probably more connected to me as an individual than if I was just a patient in and out' *(FGD/c)*. Transplant professionals were generally assessed positively and their professionalism was foregrounded: 'it was straightforward and terribly well cared for and everything's professionally looked at' *(FGD/b)*.

Participants who had donated tended to characterise their relationships with the transplant staff equal, with professional and donor working together as an egalitarian team: 'I didn't feel as though I was a patient, I felt as though I was engaged with something with professional people that were enabling me to do something' *(FGD/b)*.

Participants who did not donate also assessed transplant professionals positively: 'everything the team did were amazing' *(FGND/c)*. However, a personal connection with them was less apparent. The FGND group tended to describe their experience of transplant professionals in more abstract terms, focusing on formal descriptions of their roles and actions and referring to them using indefinite third person pronouns. One participant described the relationship between prospective donor and professional in decidedly separate terms of 'us and them': 'it's a difficult job, they're dealing with seriously ill people and with people like us' *(FGND/e)*.

Closer connections and a more meaningful relationship with transplant professionals may have developed in participants who had donated because they spent more time with those professionals and were cared for by them after their surgery. They may also have perceived a fulfilment of a shared goal between the two parties; that is to successfully and safely fulfil the autonomy of the donor and transplant a patient with end-stage renal disease. Withdrawal from the UKD process may prematurely curtail this union of professional and prospective donor.

Theme 4: Perspectives on publicity

Both groups stressed that UKD is not well understood outside transplant circles. Those who had donated felt it was important for the public to understand the need for donor kidneys, and that perhaps there was a lack of urgency among the general public in trying to resolve the issues related to organ shortages: 'it's about appreciating that there's a problem and really understanding the lack of commitment in being able to solve it' *(FGD/d)*. Participants in the non-donating group emphasised that greater public awareness about UKD may normalise the practice and help reduce the hostility they experienced when telling people about their wish to become an unspecified donor: 'if there [was] more publicity and people talking about why I've done this it might be considered more normal' *(FGND/d)*. These perspectives may also reflect the differing senses of completeness experienced by the two groups. Participants who had donated were able to draw on thoughts of having 'done their bit' to address the need for donor kidneys. Those who had not donated were understandably unable to draw on their experiences in the same way, which may explain why their discussions identified the need to normalise UKD within the general population, firstly to encourage others to come forward as UKDs and secondly to moderate the response of people to those who do come forward.

The potency of personal donation stories in generating publicity for UKD was acknowledged in both groups with some reluctance. This hesitancy arose from fears that publishing stories about donors and their recipients could threaten anonymity and the protection it provides from the negative outcomes of donation: 'all of us largely come from not wanting to contact with the recipients but there are some good stories that people have been in contact with their donor' *(FGD/a)*. An additional concern that arose in the non-donating group was how the motivation of donors coming forward to tell their story might be received: 'if they want to be looked at as a hero, well, mmm … if it's in order to create publicity then that's different, these things are not easily distinguished' *(FGND/d)*.

This difference in perspective between the two focus groups continued in discussions about how publicity should be focused. In the donated group, participants expressed a willingness to help raise awareness about UKD using their own experiences and reasoning. This extended to a desire to work with transplant professionals to support prospective donors: 'it would be persuasive if the professionals would say, "Come on, work with us to help us to help these people!"' *(FGD/b)*. This further supports the comments made as part of *Theme 3* with regard to UKDs feeling like part of the transplant team.

In the non-donating group, participants were hesitant to become publicly involved themselves, delegating this role to celebrities or other unspecified people who were referenced with indefinite third-person pronouns: 'if you've got the kind of personality that can do it – I don't think I have, I wouldn't have found it easy to discuss. Maybe someone in EastEnders needs to do it' *(FGND/e)*. This suggests that completing the process led to UKDs feeling confident in their knowledge of UKD and that their personal experience validated their desire to encourage other people to donate. Those who had not donated lacked this confidence and appeared uncomfortable with the notion of involving donors in publicising UKD.

Conclusions

Qualitative outcomes

This study demonstrated notable differences in perception of the UKD process between how those who proceed to donation and those who do not. These differences may be summarised by two psychosocial dynamics: responsibility and completeness. Participants who donated expressed the importance of anonymity in freeing them from responsibility towards their recipient. Anonymity enabled them to accept their donation regardless of the outcome, thus protecting against any negative psychological consequences. This finding concurs with research that indicates UKD is rarely associated with negative psychological outcomes.[24] The use of personal stories of recipients and donors to promote UKD was not preferred by either group, as it threatens anonymity.

Mutual responsibility was evident in discussions of the role of the family. Participants who had donated exhibited empathy, indicating they felt responsible for the anxiety they had subjected their family to. Participants who had not donated displayed implicit acknowledgement of their responsibility to involve the family in the decision to donate, and asserted their families' responsibility to respect their freedom of choice. The desirability of a sense of completeness to the donation process was woven into participants' talk on all themes. For those who had donated, anonymity was a barrier to the satisfying sense of completeness that may accompany contact with the recipient. Those who did not donate constructed counterfactual scenarios in which they imagined negative outcomes of their donation attempt, had it gone ahead. This may have implications for coping following withdrawal.[8,24]

A sense of completeness seems to manifest in those who proceeded to donation in a confident and positive understanding of their position in relation to the healthcare professionals they encountered. The relationship was constructed as egalitarian, with all parties working together to achieve a mutual goal. This was absent among withdrawn donors, suggesting a sense of completion of the donation process consolidates the roles and relations between professional and donor. This extends the findings of previous research which reported a link between UKD and the development of 'connections to others'.[11] Completed participants also appeared more confident about the role of donors in promoting UKD, a sentiment that may have emerged from seeing the process through to the finish. Participants who did not donate lacked this experience and felt that they were unlikely to be the most appropriate people to be publicising UKD to others.

Finally, the issue of family support for UKD was highlighted in particular by the group who had not proceeded to donation, and this was the same for both those who had been withdrawn by the medical team and the individual who had decided not to proceed. They associated the negativity experienced from their own families to be a consequence of poor awareness of the practice in the general population. Accordingly, they favoured the notion that publicity should normalise the act of UKD to not only raise the profile of UKD but also mitigate unfavourable reactions to those coming forward as potential donors. A possible explanation for the non-donating group highlighting the negativity displayed by their families is that these experiences were the most salient memories held by these individuals who were not able to see their donation through. Those who donated also may have experienced similar resistance, but this may have been less salient than the thoughts and feelings that arose from successfully donating. The significance of the role of family in this study concurs with previous research into how the family supports UKD.[32]

Strengths and limitations

A major strength of this study is that it included the perspectives of those who experienced the workup process for UKD, however did not donate. The focus group method of data collection enabled detailed accounts of participants' experiences to emerge naturally through consensus and disagreement within the group, generating insights which may have been missed in a one-on-one interview. The study was limited by the small number of participants, and it is unlikely that data saturation was achieved. As only one participant had self-withdrawn, the understanding this study can provide into the experiences of individuals who self-withdraw is restricted. In addition, all of our participants were recruited from a single transplant centre. Variations in practices and the attitude of healthcare professionals between centres are likely to influence the experiences of potential donors.

Recommendations

Arguably, there is an obligation to ensure that those who withdraw or who are withdrawn from the UKD process should nevertheless have a positive experience of the process. This is problematic, as it appears that a sense of completeness, which is associated with donation, is an important component of a positive overall experience. To counteract any potential sense incompleteness for those who withdraw/are withdrawn, progression to donation could be redefined into distinct stages. For example, an initial information and 'counselling' stage leading to a decision about whether to proceed, followed by second stage involving the medical workup towards donation. Appropriate counselling could be delivered following withdrawal at each stage to help process negative feelings that arise from apparently not progressing to some point of completion and to bring closure to individuals' experiences. An intervention based on motivational interviewing to prevent unresolved ambivalence has shown promise in promoting positive outcomes for live donors[33] and may also be beneficial in those who do not proceed.

Attention to the roles, responsibilities and perceptions of the prospective donors' family may prove useful, even at the point of initial contact. Encouraging potential UKDs to involve their families early may be beneficial in order for all parties to benefit from the support and expertise of the transplant team. Open discussions regarding the individual's motivations to donate, the process and the risks may help potential donors who fear the reactions of their family. A fuller analysis of the experiences of individuals who withdraw themselves, or who are withdrawn from the UKD scheme, is needed, and this study demonstrates that there is willingness on the part of affected individuals to engage in such research.

Appendix 3 A health economic analysis of unspecified kidney donation

Aims

1. To compare service use and costs between directed and undirected donors.
2. To compare health-related quality of life between directed and undirected donors.
3. To estimate the broader cost-effectiveness of undirected donation.

Methods

The data described in this chapter were derived from the data set generated by the study reported in RA5, where the detailed questionnaire methodology is described. We report here an economic analysis based on these data.

Service use and costs

Service use was measured using the CSRI.[34] The CSRI asked participants for details of services used in the 6 months prior to baseline and then the period up to pre-operation assessment, 3-month follow-up and 12-month follow-up. Information was collected on how many contacts took place and, for some services, what the typical duration was. For inpatient care, information was collected on number of days spent in hospital.

Costs were calculated by combining the service use data with appropriate unit costs. These were taken from the annual compendium produced by the University of Kent[35] and NHS Reference Costs.[36] Inpatient care was costed using episode costs or day costs depending on the reason for the admission. A list of unit costs is provided in *Appendix 3*, *Table 6*.

Analyses reported in this section are for those who donated, and comparison is made between specified and unspecified donations. Descriptive statistics are presented for individual services. Inpatient costs are reported excluding the costs of the actual donation. This would apply to all donors and would dominate all other costs. The total costs at each time point were compared between specified and unspecified d onors, and 95% confidence intervals (CIs) around the cost difference were generated using bootstrap methods. The costs over the whole follow-up period were combined, and differences compared controlling for both baseline and pre-operation costs. (The CSRI asked for service use since the previous questionnaire and so if data at 3-month follow-up were missing, we assumed that the 12-month follow-up covered the whole period.)

Health-related quality of life

The SF-12v2 was used at baseline, 3-month follow-up and 12-month follow-up to measure health-related quality of life.[37] This was subsequently used to derive a utility score via the Short Form questionnaire-6 Dimensions (SF-6D) algorithm.[38] The score can range from 0.31 ('worst health state') to 1 ('full health'). Comparisons were made between specified and unspecified donors at each time point.

TABLE 6 Unit costs (2019–20 £s)

Service	Unit cost	Unit	Source
General practitioner	3.70	Minute	Curtis and Burns (2020)[35]
Surgeon	331	Contact	Department of Health (2021)[36]
Nephrologist	170	Contact	Department of Health (2021)[36]
Psychologist	201	Contact	Department of Health (2021)[36]
Other doctor	135	Contact	Curtis and Burns (2020)[35]
Nurse	0.70	Minute	Curtis and Burns (2020)[35]
Transplant nurse	0.70	Minute	Curtis and Burns (2020)[35]
Counsellor	88	Contact	Department of Health (2021)[36]
Complementary health care	1.00	Minute	Assumption
Inpatient	Various	Episode/day	Department of Health (2021)[36]
Accident and emergency	182	Visit	Department of Health (2021)[36]
Blood test	3.67	Test	Department of Health (2021)[36]
X-ray	33.61	Investigation	Department of Health (2021)[36]
MRI	143.72	Investigation	Department of Health (2021)[36]
CT	72.47	Investigation	Department of Health (2021)[36]
Kidney ultrasound	52.45	Investigation	Department of Health (2021)[36]
Other ultrasound	52.45	Investigation	Department of Health (2021)[36]
Kidney biopsy	892.98	Investigation	Department of Health (2021)[36]
Cystoscopy	492.39	Investigation	Department of Health (2021)[36]
Echocardiogram	79.95	Investigation	Department of Health (2021)[36]
Angiogram	1130.01	Investigation	Department of Health (2021)[36]

Cost-effectiveness modelling of unspecified donation

We had originally planned to conduct long-term modelling of undirected donation in terms of the broader impact on recipients of kidneys. The modelling strategy has, though, evolved given (1) the results from the analyses on service use, costs and health-related quality of life for donors and (2) the recognition that good evidence already existed regarding the cost-effectiveness of kidney transplantation compared to dialysis for people with renal failure. As such, the approach adopted and reported here has been to investigate the economic benefits of increasing the number of people who make an undirected donation and to use existing data on costs and effectiveness for those in receipt of kidneys for this modelling.

It was unnecessary to use a decision-analytic or Markov model for this purpose. We take into account a number of factors, and make assumptions regarding these, to estimate cost-effectiveness. These are:

- In order to increase the number of undirected donations, a national campaign is required, and this comes at a cost. We have arbitrarily assumed the cost to be £5M in the initial analyses.
- The effectiveness of the campaign is measured in terms of the extra number of unspecified donations.
- One of the potential benefits of undirected donation is that it initiates a chain of transplants. We have assumed a typical chain length of three.
- It is assumed that there is a cost to donating, including the pre-operation assessments, the operation itself and aftercare. Given the results presented later and information from the NHS Reference Costs, we have assumed this cost to be £5000.

- While donation is considered reasonably safe, it is likely that the donor will experience some discomfort that will affect quality of life, albeit for a short period of time. We used data from the SF6D to estimate QALYs for donors during the year of their donation. This was estimated at being 0.039 less than if donation had not taken place.
- For recipients of kidneys, there will be costs incurred. These include the cost of the transplant and the cost of immunosuppressant treatment. In the first year, this is estimated at £17,840, and in subsequent years at £5000.[39]
- It is assumed that a patient receiving a kidney has 1 year less on dialysis. After the year, they too would receive a kidney, and it is assumed this from a cadaver.
- A year on dialysis is assumed to cost £30,800.[39]
- The QALY gain from a kidney transplant is assumed to be 0.37.[40] However, in the year of the transplant, we assume it is half this (0.185) due to discomfort and pain from the operation.

Using the above assumptions in an Microsoft Excel (Microsoft Corporation, Redmond, WA, USA) sheet allows us to estimate the incremental cost per QALY gained, following a campaign to increase undirected kidney donations. Given the uncertainty of the parameter values, we conduct a series of one-way sensitivity analyses to see how important the assumptions are for the results. These sensitivity analyses are: (1) reducing the campaign cost to £1M, £2M and £4M; (2) reducing chain size to two and increasing it to four; (3) increasing cost of donation by 25% and 50% and (4) increasing transplant costs by 25% and 50%. We do not change the success rate of the campaign but rather report the success rate for each sensitivity analysis at which the campaign is cost-effective at £20,000 per QALY gained.

Results

At baseline, CSRI data were available on 204 specified donors and 169 undirected donors. The figures for the other periods were: pre-operation assessment, 117 specified and 137 unspecified; 3-month follow-up, 52 specified and 63 unspecified; and 12-month follow-up, 153 specified and 136 unspecified.

Percentage using services

Appendix 3, *Table 7* shows the percentage of each group using services. In the period up to baseline, just under half of each group had general practitioner (GP) contacts. Slightly more of the specified group reported having seen a surgeon and a nephrologist than the unspecified group. The unspecified groups were noticeably more likely to have had contacts with a psychologist. Slight fewer than three-quarters of each group had seen a transplant nurse. Most participants reported having had a blood test. The specified group were more likely to report having had CT scans, ultrasounds and echocardiograms.

In the period up to pre-operation assessment, most participants reported contacts with a surgeon and slightly fewer than half with nephrologists. Around two-thirds of each group reported transplant nurse contacts, and most again had blood tests. The unspecified group were again relatively more likely to have had psychologist contacts.

During the 3-month follow-up period, around two-thirds of each group had contacts with a surgeon and two-thirds also with a transplant nurse. The unspecified group were slightly more likely to have had GP contacts. There were few other large differences between the groups, and contacts with psychologists were now reduced for the unspecified group.

Finally, during the 12-month follow-up period, relatively large numbers in each group reported having had GP contacts. Most had blood tests. There were few large differences between the groups for any services.

Mean number of service contacts

The figures in *Appendix 3*, *Table 8* are the mean number of contacts just by those using services (i.e. excluding those with no contacts). It can be clearly seen that for those using services, the intensity of use was generally low and similar between the groups at each time point. The number of contacts with counsellors and complementary healthcare services show the greatest variation.

Mean cost of services

In the period prior to baseline assessment, the services with the highest costs were contacts with surgeons, neurologists and angiograms (see *Appendix 3*, *Table 9*). Most costs were relatively small given the large number of people with no contacts with specific services. During the period up to the pre-operation assessment and the psychologist, costs were noticeably higher for the unspecified group. Most other differences were relatively small. The costs at 3-month follow-up were highest for contacts with surgeons, and this was similar for the two groups. Finally, at 12-month follow-up, the costs were highest for inpatient care, with these being greater for the specified group. Costs were low for most other services with few key differences between the groups.

At baseline, mean total costs were £124 lower for the unspecified group (bootstrapped 95% CI −£289 to £53). During the pre-operation period, the costs for the

TABLE 7 Percentage of specified and unspecified donors using specific services in the period prior to each time point

	Baseline		Pre-op		3-month follow-up		12-month follow-up	
Service	Specified (n = 204)	Unspecified (n = 169)	Specified (n = 117)	Unspecified (n = 137)	Specified (n = 52)	Unspecified (n = 63)	Specified (n = 153)	Unspecified (n = 136)
General practitioner	49	48	18	21	31	44	40	49
Surgeon	50	40	60	54	65	67	18	24
Nephrologist	70	55	44	47	40	44	23	21
Psychologist	15	40	9	39	2	11	3	2
Other doctor	17	13	14	15	4	2	9	9
Nurse	35	28	12	13	35	16	23	30
Transplant nurse	70	72	63	67	62	65	26	33
Counsellor	13	12	7	12	6	5	4	4
Complementary health care	6	5	3	4	2	0	5	8
Inpatient	3	2	3	1	8	8	7	7
Accident and emergency	3	7	0	6	8	11	11	9
Blood test	94	85	70	80	79	79	66	68
X-ray	76	61	34	41	15	17	9	14
MRI	35	28	15	29	8	11	7	7
CT	61	43	24	31	13	11	6	6
Kidney ultrasound	63	48	30	35	13	8	3	4
Other ultrasound	22	9	8	9	13	3	8	7
Kidney biopsy	3	2	3	4	4	0	1	0
Cystoscopy	5	3	3	4	4	0	1	1
Echocardiogram	43	27	27	28	8	6	4	2
Angiogram	9	9	7	11	4	0	1	1

unspecified group were £120 higher (bootstrapped 95% CI −£117 to £339). At 3-month follow-up, the costs were £112 lower (bootstrapped 95% CI −£456 to £219). Finally, at 12-month follow-up, the unspecified group had mean costs that were −£144 lower than for the specified group (bootstrapped 95% CI −£830 to £348). The CIs show that none of these differences were statistically significant.

The mean costs over the whole follow-up period were £937 for specified donors and £778 for unspecified donors. The mean costs were £330 lower for unspecified donors difference when baseline, and pre-operation costs were controlled for, but again this was not statistically significant (bootstrapped 95% CI −£1225 to £564).

SF6D utility scores

At baseline, the mean utility score was 0.0059 higher for the unspecified group (95% CI −0.016 to 0.026) (see *Appendix 3*, *Table 10*). At 3-month follow-up, the score was 0.026 higher for the unspecified group (95% CI −0.002 to 0.054). By 12-month follow-up, the score was 0.002 higher for the unspecified group (95% CI −0.026 to 0.031). These CIs show that the differences were not statistically significant.

TABLE 8 Mean number of contacts with specific services by specified and unspecified donors in the period prior to each time point

Service	Baseline		Pre-op		3-month follow-up		12-month follow-up	
	Specified (*n* = 204)	Unspecified (*n* = 169)	Specified (*n* = 117)	Unspecified (*n* = 137)	Specified (*n* = 52)	Unspecified (*n* = 63)	Specified (*n* = 153)	Unspecified (*n* = 136)
General practitioner	1.6	1.5	1.3	1.5	1.4	1.6	2.0	2.1
Surgeon	1.2	1.2	1.2	1.1	1.7	1.4	1.5	1.6
Nephrologist	1.6	1.4	1.3	1.3	1.3	1.4	1.3	1.3
Psychologist	1.3	1.2	1.4	1.1	1.0	2.0	2.2	2.7
Other doctor	1.5	1.5	1.4	1.2	5.5	1.0	1.8	1.9
Nurse	1.4	1.3	1.4	1.2	1.4	1.4	1.7	1.5
Transplant nurse	2.5	2.6	2.2	2.5	2.3	2.3	1.4	1.9
Counsellor	1.2	4.0	1.0	1.8	1.7	1.0	8.4	4.3
Complementary health care	2.5	3.8	1.0	1.3	1.0	–	3.9	5.4
Inpatient	1.0	1.0	1.3	1.0	1.3	1.2	1.1	1.1
Accident and emergency	1.2	1.3	–	1.1	1.3	1.3	1.1	1.5
Blood test	2.9	2.6	2.3	2.5	2.1	2.2	1.5	2.0
X-ray	1.2	1.2	1.3	1.2	1.0	1.2	1.0	1.1
MRI	1.0	1.1	1.1	1.0	1.0	1.3	1.2	1.4
CT	1.1	1.1	1.1	1.0	1.1	1.0	1.1	1.3
Kidney ultrasound	1.0	1.0	1.1	1.0	1.0	1.0	1.0	1.0
Other ultrasound	1.0	1.1	1.0	1.0	1.0	1.0	1.3	1.1
Kidney biopsy	1.0	1.0	1.0	1.0	1.0	–	1.0	–
Cystoscopy	1.1	1.0	1.0	1.0	1.0	–	1.0	1.0
Echocardiogram	1.0	1.0	1.1	1.2	1.0	1.0	1.2	1.7
Angiogram	1.0	1.0	1.1	1.1	1.5	–	1.0	1.0

Cost-effectiveness modelling

The results from the cost-effectiveness modelling are shown in *Appendix 3*, *Table 11*. It shows the costs and QALYs associated with increased numbers of unspecified donations per year. Incremental QALYs and costs from donation relate directly to these numbers. The incremental costs and QALYs for recipients relate to both the number of new donations and also the assumed chain length of three. Total costs and QALYs are the sum of the incremental costs and QALYs for donors and recipients, and the ICER is the ratio of these. It can be seen that the ICER is very high the smaller the number of new donations. The number required to demonstrate cost-effectiveness (i.e. below £30,000 per QALY) is 50.

The results from the sensitivity analyses are as follows:

- If the cost of the campaign is reduced to £4M, £3M, £2M or £1M, then the number required to achieve cost-effectiveness would be 40, 30, 20 and 10, respectively.
- If the chain size is reduced to two, then the number required would be 80. If it is increased to four, then a success rate of 40 would be sufficient to demonstrate cost-effectiveness.
- Increasing the donation cost by 25% or 50% has little impact, and 50 are still required to show cost-effectiveness.

Discussion

These analyses have shown that kidney donors, whether unspecified or specified, use a wide range of healthcare services. There is some evidence that unspecified donors are more likely to see psychologists than are specified donors. While the use of psychologists being greater in the unspecified group is expected, it was also intended

TABLE 9 Mean cost of contacts with specific services by specified and unspecified donors in the period prior to each time point (2019–20 £s)

Service	Baseline		Pre-op		3-month follow-up		12-month follow-up	
	Specified (*n* = 204)	Unspecified (*n* = 169)	Specified (*n* = 117)	Unspecified (*n* = 137)	Specified (*n* = 52)	Unspecified (*n* = 63)	Specified (*n* = 153)	Unspecified (*n* = 136)
General practitioner	30	24	13	11	17	24	34	40
Surgeon	203	157	240	203	369	310	89	129
Nephrologist	193	127	97	103	92	108	51	44
Psychologist	38	95	26	89	4	45	14	12
Other doctor	34	26	25	25	29	2	20	23
Nurse	4	3	1	1	4	1	3	3
Transplant nurse	59	47	28	29	15	18	4	7
Counsellor	14	44	6	20	8	4	29	17
Complementary health care	6	7	1	2	1	0	9	40
Inpatient	40	37	55	8	95	113	379	171
Accident and emergency	6	15	0	12	18	26	23	24
Blood test	10	8	6	7	6	6	4	5
X-ray	31	24	15	17	5	7	3	5
MRI	51	43	23	43	11	21	12	15
CT	47	33	19	23	11	8	5	5
Kidney ultrasound	34	26	17	19	7	4	1	2
Other ultrasound	12	5	4	5	7	2	5	4
Kidney biopsy	26	16	23	39	34	0	6	0
Cystoscopy	27	15	13	22	19	0	3	4
Echocardiogram	36	22	24	26	6	5	4	3
Angiogram	100	100	87	140	65	0	7	8
Total	991	867	719	840	815	703	701	557

TABLE 10 Mean SF6D utility scores at baseline, 3-month follow-up and 12-month follow-up comparing specified and unspecified donors

	Specified		Unspecified	
	N	Mean	*N*	Mean
Baseline	201	0.857	168	0.862
3-month follow-up	156	0.792	148	0.817
12-month follow-up	150	0.817	135	0.819

that all would have contact with a psychologist. When the baseline and pre-operation periods were combined, the use of psychologists was 73% in the unspecified group and 28% in the specified group. This still suggest a level of under-reporting, which may be expected with self-report data. Also, participants may have reported use of other professionals when in fact these may have been psychologists.

TABLE 11 Base-case cost-effectiveness results

New donations	Cost of donation (£s)	QALY loss for donors	Cost for recipients y1 (£s)	QALY gain for recipients	Total cost (£s)	Total QALY	ICER (£s)
5	25,000	0.19	−380,487	5.51	4,644,513	5.32	873,161
10	50,000	0.39	−760,974	11.02	4,289,026	10.64	403,165
15	75,000	0.58	−1,141,461	16.54	3,933,539	15.96	246,500
20	100,000	0.77	−1,521,948	22.05	3,578,052	21.28	168,167
25	125,000	0.97	−1,902,435	27.56	3,222,565	26.60	121,167
30	150,000	1.16	−2,282,922	33.07	2,867,078	31.92	89,834
35	175,000	1.35	−2,663,409	38.59	2,511,591	37.23	67,454
40	200,000	1.54	−3,043,896	44.10	2,156,104	42.55	50,668
45	225,000	1.74	−3,424,383	49.61	1,800,617	47.87	37,613
50	250,000	1.93	−3,804,870	55.12	1,445,130	53.19	27,168
55	275,000	2.12	−4,185,357	60.63	1,089,643	58.51	18,623
60	300,000	2.32	−4,565,843	66.15	734,157	63.83	11,502
65	325,000	2.51	−4,946,330	71.66	378,670	69.15	5476
70	350,000	2.70	−5,326,817	77.17	23,183	74.47	311
75	375,000	2.90	−5,707,304	82.68	−332,304	79.79	−4165
80	400,000	3.09	−6,087,791	88.20	−687,791	85.11	−8081
85	425,000	3.28	−6,468,278	93.71	−1,043,278	90.43	−11,537
90	450,000	3.47	−6,848,765	99.22	−1,398,765	95.75	−14,609
95	475,000	3.67	−7,229,252	104.73	−1,754,252	101.06	−17,358
100	500,000	3.86	−7,609,739	110.24	−2,109,739	106.38	−19,831

ICER, incremental cost-effectiveness ratio.

Overall costs are very similar between both types of donors. Health-related quality of life is also similar for both groups, and the reduction in quality of life following donation is small. We can conclude from these analyses that there are no substantial cost-effectiveness implications of unspecified donation at the level of the donor. However, increasing unspecified donation may be highly cost-effective if it results in a chain of transplants.

To increase donations may require a campaign, and we have been able to investigate the cost-effectiveness of doing this. A campaign costing £5M with a moderate success rate would most likely not save money unless new donations increase by more than 50 but would still appear to represent good value for money. Of course, the £5M is an arbitrary figure but is in line with other public health campaigns. We have been conservative in our assumptions given the preliminary nature of the model.

There were limitations with these analyses. One limitation is that we relied on donor self-report of service used, and under-reporting may have occurred. There was, though, no reason to expect this to have been different between the groups, and it was the only way in which to obtain information on a comprehensive range of services. A further limitation was that the modelling relied on assumptions to be made about various parameters. These assumptions were, though, addressed using a series of sensitivity analyses.

Appendix 4 Psychometrics for the 'Acceptance of UKD' score

The following items were collated to form the 'Acceptance of UKD' scale. These were answered on a 5-point Likert scale ('strongly agree' to 'strongly disagree').

	Question	Label	*N*	Mean	SD	Min	Max
1	Individuals making initial enquiries regarding unspecified (non-directed altruistic) donation receive an enthusiastic response when contacting my centre	cenenthu	151	0.9	0.8	0	3
2	Sufficient clinical facilities are currently available in my centre to allow unspecified (non-directed altruistic) donation	cenfacil	151	0.9	1.0	0	4
3	There is currently sufficient support at a national level to help my centre with any queries or problems regarding unspecified (non-directed altruistic) donation	cennatsupp	151	1.2	0.8	0	4
4	Sufficient staff training is currently available at my centre to allow unspecified (non-directed altruistic) donation	centrain	152	1.3	1.0	0	4
5	I am confident dealing with people wishing to become unspecified (non-directed altruistic) kidney donors	ukdconf	151	0.7	0.8	0	4
6	My experience with people wishing to become unspecified (non-directed altruistic) donors has been generally positive	ukdposv	152	0.9	0.7	0	3
7	I am comfortable with unspecified (non-directed altruistic) donors undergoing major surgery	ukdsurg	152	0.9	0.7	0	3

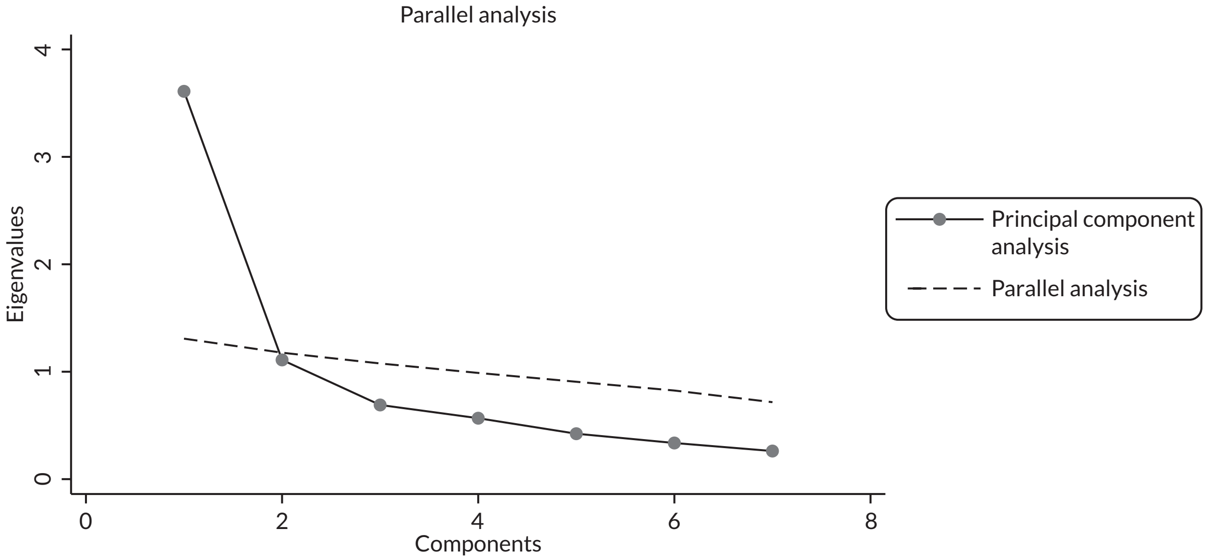
Max, maximum, Min, minimum; SD, standard deviation.

Inter-item correlations

	cenenthu	cenfacil	cennatsupp	centrain	ukdconf	ukdposv	ukdsurg
cenenthu	1						
cenfacil	0.34	1					
cennatsupp	0.39	0.46	1				
centrain	0.25	0.62	0.42	1			
ukdconf	0.39	0.37	0.48	0.37	1		
ukdposv	0.48	0.26	0.38	0.32	0.65	1	
ukdsurg	0.41	0.4	0.42	0.32	0.64	0.67	1

The first principal component of the correlation matrix explained 52% of the variance in responses to the acceptance items. Assuming the first principal component represents acceptance, this indicates that factors other than acceptance explain relatively little additional variation in responses. Parallel analysis indicated that the items are likely to form a unidimensional scale. The plot below shows that only the eigenvalues of the first principal components (solid line) are above those expected by chance (dashed line).

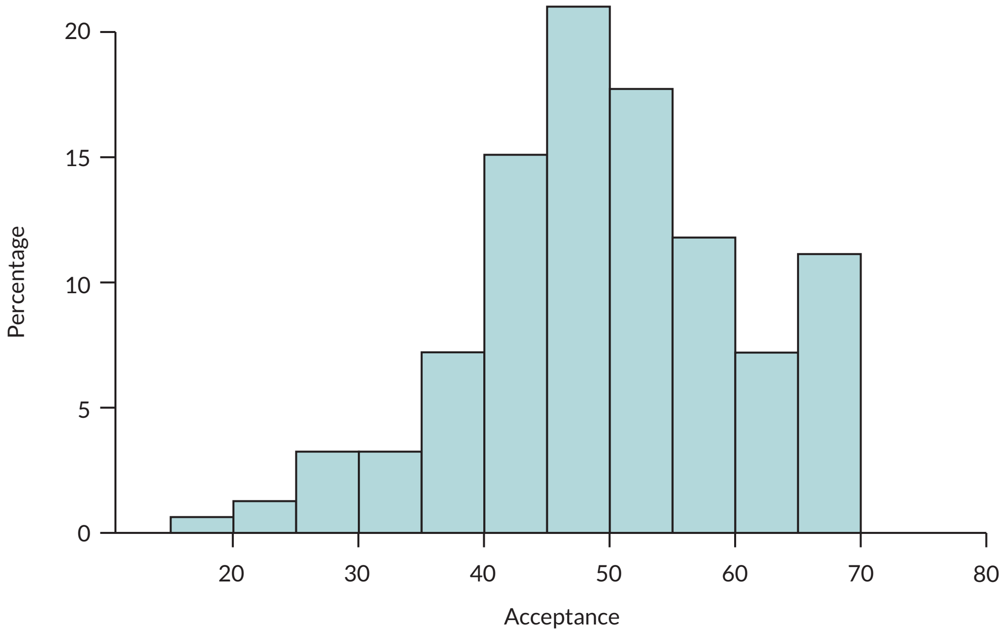
This synopsis should be referenced as follows:
Mamode N, Norton S, McCrone P, Chilcot J, Draper H, Gogalniceanu P, *et al.* Barriers to and outcomes of unspecified kidney donation in the UK: BOUnD, a mixed-methods study. *Health Soc Care Deliv Res* 2025;**13**:20. https://doi.org/10.3310/RTEW9328



Reliability assessed using Cronbach's alpha indicated that forming the items into a scale produced a scale within the bounds of what is generally considered acceptable (i.e. alpha > 0.7).

Item	*N*	Sign	Item-total correlation	alpha
cenenthu	151	+	0.60	0.76
cenfacil	151	+	0.62	0.76
cennatsupp	151	+	0.67	0.75
centrain	152	+	0.59	0.76
ukdconf	151	+	0.70	0.74
ukdposv	152	+	0.69	0.74
ukdsurg	152	+	0.72	0.73
Total score				0.78

The total acceptance score was calculated, where higher scores indicate greater acceptance of UKD. To account for differing response categories across items, the scale of the score was standardised with the mean for the sample set at 50 and the standard deviation of 10. This is an arbitrary scale but allows for comparisons across groups within the sample. The distribution was approximately normal with mild positive skew.



Crude means across role groups

	N	Mean	Standard deviation
Co-ordinator or nurse	45	49.1	10.2
Physician/surgeon	69	50.3	11.7
Other	38	50.5	8.4
Total	152	50.0	10.4

Adjusted means across groups were not significant and are provided in the main manuscript. Correlations between support and other variables were calculated and are also provided in the main manuscript.

This synopsis should be referenced as follows:
Mamode N, Norton S, McCrone P, Chilcot J, Draper H, Gogalniceanu P, *et al.* Barriers to and outcomes of unspecified kidney donation in the UK: BOUnD, a mixed-methods study. *Health Soc Care Deliv Res* 2025;**13**:20. https://doi.org/10.3310/RTEW9328