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What factors explain the association between socioeconomic deprivation and reduced likelihood of live-donor kidney transplantation? A questionnaire based pilot case-control study

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2 **What factors explain the association between socioeconomic deprivation and reduced**
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4 **likelihood of live-donor kidney transplantation? A questionnaire based pilot case-control study**
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Abstract**Objectives**

Socioeconomically deprived individuals with renal disease are less likely to receive a live-donor kidney transplant than less deprived individuals. This study aimed to develop and pilot a questionnaire designed to determine what factors explain this association.

Design

Questionnaire development and a pilot case-control study. Primary aims were to develop and evaluate a questionnaire, assess response rates and to generate data to inform full-scale study design.

Setting

A UK tertiary renal referral hospital and transplant centre.

Participants

Invited participants comprised 30 live-donor kidney transplant recipients (cases) and 30 deceased-donor kidney transplant recipients (controls). Participants were randomly sampled from all adults who had been transplanted at Southmead Hospital, North Bristol NHS Trust between 1/8/2007 and 31/7/13.

Methods

Participants were posted questionnaires accompanied by an invitation letter from the renal consultant responsible for their care, and a patient information leaflet. Non-responders were sent a second questionnaire after 4-6 weeks. Data was extracted from returned questionnaires and entered onto a REDCap™ database.

Results

1 63% (n=38) of those invited returned questionnaires. 16 (42%) declined to answer the question on
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4 income. 58% of participants had not asked any of their potential donors to consider living kidney
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6 donation (52% LDKT vs 65% DDKT, p=0.44). There was some evidence of a difference between the
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8 R3K-T knowledge score for recipients of LDKTs (Mean 6.7, SD 1.8) and for recipients of DDKTs
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10 (Mean 4.9, SD 2.1), p=0.008. Variable distribution for the exposure variables of interest were
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12 determined.
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15 **Conclusions**

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17 Findings from this study will inform a sample size calculation for a full-scale study. The findings of
18
19 the full-scale case-control study will help us better understand how socioeconomic deprivation is
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21 related to the type of transplant an individual receives. This understanding will help us to design
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23 and appropriately tailor an intervention to reduce inequitable access to live-donor kidney
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25 transplantation.
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Strengths and limitations of this study

- Pilot studies are a key phase of study development and design, essential for evaluating any new research instrument, and for informing the design of a full-scale study.
- The study questionnaire development has been described in detail and the questionnaire evaluated in cognitive interviews.
- The findings of this pilot study will inform a sample size calculation for a full-scale study, by providing data on frequency of exposures, and variable distribution.
- As this is a pilot study it is not designed to be powered to provide evidence for what factors explain the association between socioeconomic deprivation and reduced likelihood of live-donor kidney transplantation.

INTRODUCTION

Live-donor kidney transplantation offers the best treatment in terms of life-expectancy and quality of life (1-6) for many patients with renal failure, and the possible long-term risks of live-donor nephrectomy are small (7-11). Within the UK socioeconomically deprived individuals are less likely to receive a live-donor kidney transplant (LDKT) (12, 13) compared with less deprived individuals.

The same has been demonstrated in the Netherlands (14), the USA (15-17) and Australia (18).

Little research exists exploring the reasons for the observed inequity, and a USA Consensus Conference in 2014 on Best Practices in Live Kidney Donation concluded that there is a real need to understand the mechanisms behind these observed disparities and identify targets for intervention (19).

This study follows on from recently published qualitative work (20) in which a series of semi-structured interviews were undertaken with renal patients who had not received a LDKT. These interviews aimed to identify barriers to live-donor kidney transplantation and compared the experiences of individuals from areas of high and low socioeconomic deprivation (SED). Four factors appeared to distinguish more deprived individuals from less deprived: i) Passivity, ii) Disempowerment, iii) Lack of social support, and iv) Short-term focus. In addition to a lack of social support, the emerging themes related to low levels of patient activation, defined as an individual's knowledge, skill, and confidence for managing their health and health care (21, 22). The qualitative interviews were analysed inductively and the work thus generated hypotheses that need further exploration. The questionnaire based case-control study, of which this is a pilot, has been designed to further investigate and validate the qualitative themes, and to quantitatively examine the relationships between these variables and the type of transplant received. The qualitative study and subsequent questionnaire represent an 'exploratory sequential mixed

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2 methods design' (23) in which elaboration, enhancement, illustration and clarification of the
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4 results of one method are sought with the results from the other method (24).
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9 The proposed full-scale study of which this is a pilot has been designed to assess whether SED is
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11 associated with:
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13 i) the number of potential living kidney donors available to a transplant candidate, and their
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15 medical, surgical and psychological suitability,
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18 ii) the social support experienced by a transplant candidate,
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21 iii) a transplant candidate's beliefs and knowledge about living kidney donation and
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23 transplantation, and
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26 iv) an individual's level of engagement in their healthcare.
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30 The future full-scale case-control study will assess whether each of the variables above may be
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32 potential intermediaries in the causal pathway between SED and reduced odds of receiving a
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34 LDKT, over a deceased-donor kidney transplant (DDKT). Thus it will examine if the relationship
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36 between SED and transplant received is explained by differences in the variables listed above. This
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38 can be graphically illustrated by a Directed Acyclic Graph (see Figure 1).
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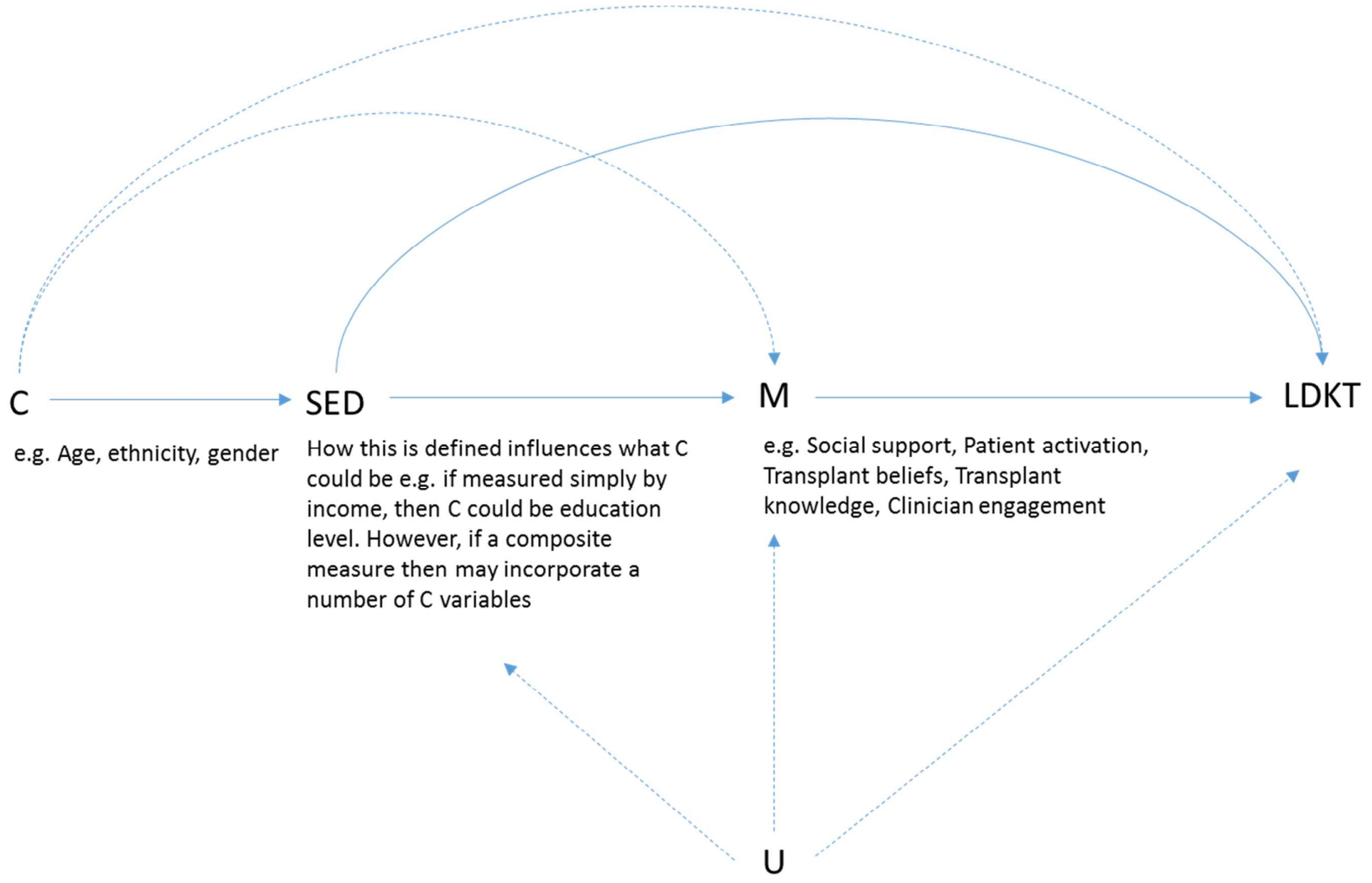


Figure 1 – Mediation Directed Acyclic Graph
 C=Measured Confounders SED=Socioeconomic deprivation M=Mediators U=Unmeasured Confounders LDKT=Live-donor kidney transplant

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2 The study presented here is a pilot of the proposed case-control study, with the aim of estimating
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4 the following important components needed to design the future larger study:
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7 i) Response rates

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9 ii) Acceptability of the questionnaires

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11 iii) Face validity of the content of the questionnaire

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14 iv) Acceptance rates of linkage of questionnaire information to medical records

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16 v) Logistics, time and costs

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18 Findings from this study were required to inform a sample size calculation for a full-scale study, by
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20 providing data on frequency of exposures, and variable distribution.
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24 25 26 **METHODS**

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29 This questionnaire-based pilot case-control study was a single centre study. Participants were
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31 recruited from Southmead Hospital, North Bristol NHS Trust and data analysis occurred at the
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33 School of Social and Community Medicine, University of Bristol. Ethical approval was provided in
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35 March 2015 by National Research Ethics Service Committee London – Bromley (Research Ethics
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37 Committee reference 15/LO/0435).
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45 **Questionnaire design**

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47 The overall study development is detailed in Figure 2. The questionnaire was designed and refined
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49 between March 2015 and July 2015. Original item generation was informed by themes arising
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51 from qualitative research (20). A literature review was then undertaken to identify existing and
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53 validated questionnaires exploring the topics we aimed to investigate. The use of existing
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55 questionnaires and validated measures allows comparison between studies and populations, and
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59 enables possible meta-analysis to be performed.
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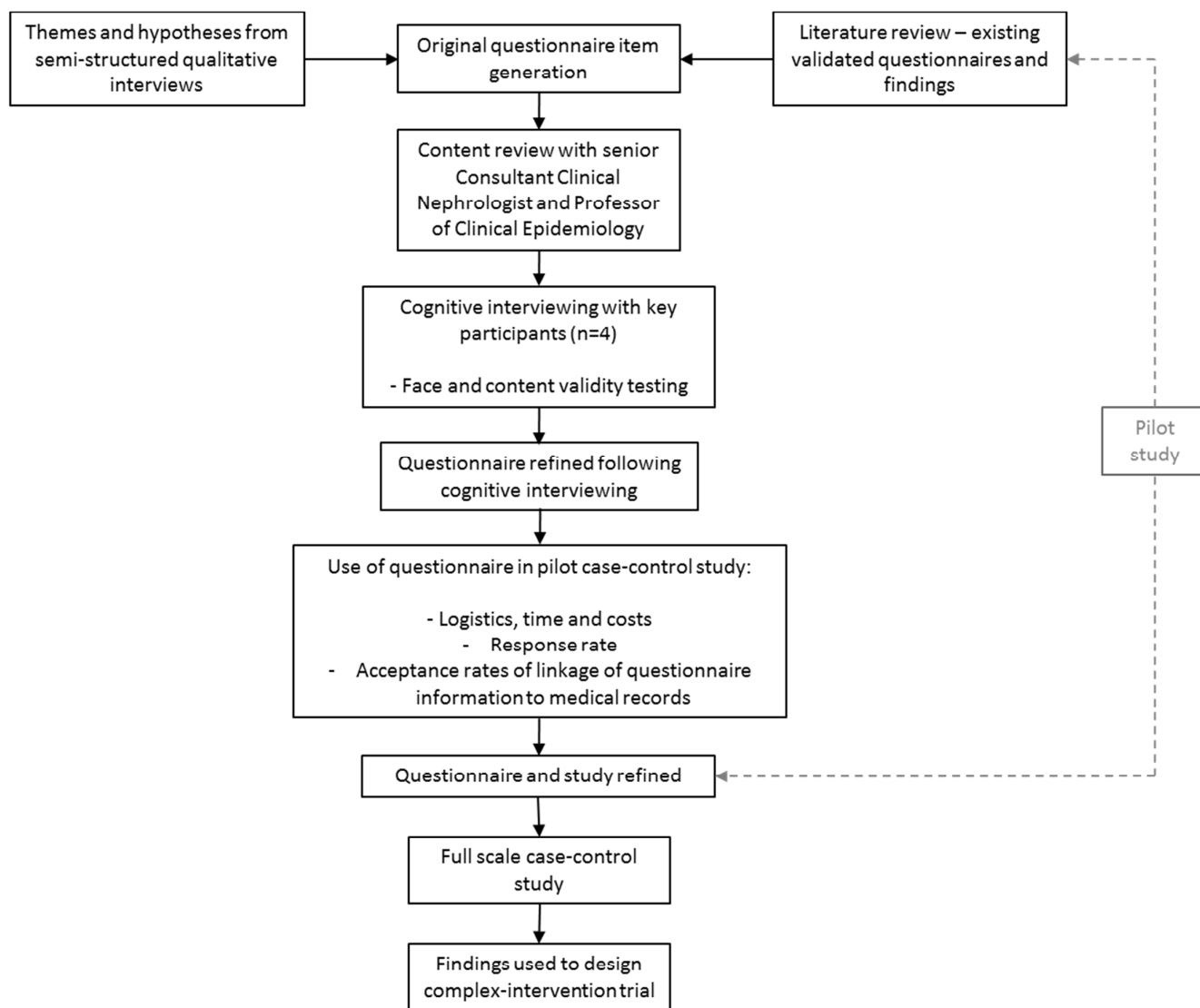


Figure 2 – Research study and questionnaire development

Questionnaire content

Individuals were asked how many potential donor relatives they had. They were asked whether any were considered suitable for donation, the reasons donors weren't considered, whether any donors volunteered, whether any were asked to donate, and whether any donors underwent assessment for donation.

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Questionnaires also assessed participant demographics, renal replacement therapy (RRT) history, and sources of health information. SED was evaluated at the individual level from education level, employment, income, and housing tenure. It was also evaluated at the area level using a postcode-derived Index of Multiple Deprivation (IMD) score (25, 26). The IMD measure is based on methodology developed at the University of Oxford Social Disadvantage Research Centre (25) and is based on routine census data. Each country in the UK has individual components constituting an IMD score (27). There are seven domains of deprivation (Income, Employment, Health and Disability, Education Skills and Training, Barriers to Housing and Services, Living Environment Deprivation, and Crime) that determine the index score for an area in England, with higher scores indicating greater deprivation. IMD scores are nationally divided into five equal-sized population quintiles according to the level of deprivation of the output area to which they belong, with the fifth quintile representing the greatest deprivation. Therefore, the IMD area-level measure of SED was used as an ecological proxy for individual SED. Both area-level and individual-level socioeconomic variables were collected to allow comparison of the two, as well as to assess the relationship between different aspects/components of SED and health behaviour and outcomes.

Survey tools

The literature review identified the following survey tools which were incorporated into this study's questionnaire:

- Social support was measured using the Interpersonal Support Evaluation List (ISEL) shortened version-12 items survey (28). The 40-item ISEL (29) is one of the most widely used instruments designed to assess perceived social support. The short form measure, ISEL-12 (28) generates a total score that describes overall perceived social support, and three subscales representing perceived availability of appraisal (advice or guidance),

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2 belonging (empathy, acceptance, concern), and tangible (help or assistance, such as
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4 material or financial aid) social support (28). The ISEL-40 has shown good internal
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6 consistency, reliability, test-retest reliability, convergent validity (29, 30) and structural
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8 validity (31). The psychometric properties of the ISEL-12 have also been assessed showing
9
10 good validity and reliability, including in populations similar to our study population in
11
12 terms of age, ethnicity and gender (32, 33). Construct validity analyses have suggested that
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14 ISEL-12 scores are positively related to social network diversity, number of people in one's
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16 social network, and life engagement, and inversely related to perceived stress and negative
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18 affect (33).
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23 • Transplant knowledge was measured using the transplant section of the Rotterdam Renal
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25 Replacement Knowledge-Test (R3K-T) (34). Prior to the development of this questionnaire,
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27 a validated and standardized test of knowledge about kidney disease and all treatment
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29 options was not available. This questionnaire was developed and validated in four groups:
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31 i) patients on dialysis, ii) patients undergoing LDKTs, iii) the general population of the
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33 Netherlands, and iv) the general population of North America. A psychometric analysis was
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35 performed using item response theory (35). This study resulted in a questionnaire, the R3K-
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37 T, which enables reliable testing of a patient's knowledge on kidney disease and treatment
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39 options in clinic and research (36).
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44 • Transplant beliefs were assessed using questions from a questionnaire from research
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46 published by Stothers et al (37, 38). Although not formally validated, the questionnaires
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48 were reviewed by three expert focus groups that included physicians, surgeons, nurses,
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50 and social workers, and piloted to test reliability. The authors report that test-retest
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52 analysis was performed, and there was no evidence of 'skew' or 'halo' effect on any subset
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54 of statements (37). No alternative questionnaire for use in this population group could be
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- An individual's level of engagement in their healthcare was measured using Insignia Health's 13 point Patient Activation Measure (PAM) (21, 22, 39). 'Patient activation' is a behavioural concept that incorporates the themes emergent from the qualitative work of passivity, disempowerment and limited knowledge. It is defined as 'an individual's knowledge, skill, and confidence for managing their health and health care.' (21, 22) The PAM was originally developed as a 22 point scale and is validated and highly reliable (40). The 13 point shortened version was subsequently developed to be less burdensome and less costly to administer and complete. The psychometric properties of the shortened version have been assessed (and compared to the 22 point scale) and the measure has been shown to be valid and reliable (21). When the 13-item PAM score is regressed on the 22-item PAM score it accounts for 92% of the variations in the 22-item version estimated activation. Construct validity assessment found that preventive behaviours, disease specific self-management behaviours, and consumeristic behaviours are all strongly correlated with PAM-13 activation scores. The 13 item version has slightly lower reliability for some subgroups, including those with lower income and education, but these lower reliabilities are still within an acceptable range (21).

The PAM is a unidimensional, probabilistic Guttman-like scale (41) that reflects a developmental model of activation. Patient Activation appears to involve four stages: 1) believing the patient role is important, 2) having the confidence and knowledge necessary to take action, 3) actually taking action to maintain and improve one's health, and 4) staying the course even under stress. The measure has good psychometric properties indicating that it can be used at the individual patient level to tailor intervention and assess changes (40). To calculate the total PAM score, the raw score is divided by the number of items answered (excepting non-applicable items) and multiplied by 13. Then, this score is

1 transformed to a scale with a theoretical range 0–100, based on calibration tables, with
2 higher PAM scores indicating higher patient activation. The raw scores can be converted
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4 into four activation levels: 1) (≤ 47.0) not believing activation important, 2) (47.1–55.1) a
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6 lack of knowledge and confidence to take action, 3) (55.2–67.0) beginning to take action
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8 and 4) (≥ 67.1) taking action.
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17 A range of different question response types were used in the questionnaire: numeric, multiple
18 choice, true/false, and scaled, using 4 and 10-point Likert items (42). Likert scaling is a bipolar
19 scaling method which measures either a negative or positive response to a question or statement.
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21 The use of even number scales is sometimes described as a ‘forced choice’ method since the
22 neutral option, which may be selected when a participant is unsure rather than truly neutral, is
23 removed.
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35 **Methods to encourage responses**

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38 In a Cochrane systematic review of methods to increase response rates to questionnaires (43), the
39 following approaches were found to be successful, and for this reason were employed in designing
40 the study questionnaire:
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- 45 - The questionnaire originated from a university (Odds Ratio (OR) of university originated
46 questionnaire versus other 1.32; 95% Confidence Interval (CI) 1.13 to 1.54, I-squared 83%)
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48 (43). Questionnaires and invitation letters were both printed with the University of Bristol’s
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50 logo.
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- The questionnaire content was of importance and interest to participants (OR 2.00; 95% CI 1.32 to 3.04, I-squared 80%) (43), as it explored a disease and treatments that the recipients all had experienced.
- The questionnaire included an assurance of confidentiality (OR 1.33; 95% CI 1.24 to 1.42) (43).
- The questionnaire was short (OR 1.64; 95% CI 1.43 to 1.87, I-squared 91%) (43, 44). The questionnaire was 14 A4 sides of size 12 font. The cognitive interviewees advised that they felt that the questionnaire was short.

Cognitive interviewing

The cognitive interview is a method that can be used 'to evaluate, and to improve, self-report survey questions, measurement instruments, research consent forms, and other written materials.' (45) The cognitive interview involves 'the administration of draft survey questions while collecting additional verbal information about the survey responses, which is used to evaluate the quality of the response or to help determine whether the question is generating the information that its author intends.' (46) Cognitive interviewing was thus undertaken to test each question for clarity, comprehension, face validity, sensitivity, acceptability, as well as the respondent's motivation to answer the question, the ease of retrieval of the required information, and the suitability of response categories. A reparative approach was taken, focussed on improving the quality of survey questions and minimising the risk of response error (45). A summary of the cognitive interview findings is available as supplementary material.

Readability

The questionnaire had a Flesch reading ease measure (47, 48) of 68.3. The higher a Flesch rating, the easier the text is to understand. A score of 68.3 corresponds to text that is written in plain English, in which the average sentence is 15-20 words long, and the average word has two syllables. This reading ease level should be easily understood by 13- to 15-year-old students.

Participant selection

30 LDKT recipients (cases) and 30 DDKT recipients (controls) were selected from all adults (age>18 years) transplanted at Southmead Hospital, North Bristol NHS Trust between 1/8/2007 and 31/7/13. Any individuals identified by their responsible clinician as lacking the mental capacity to consent to study participation according to the Mental Capacity Act 2005, were not eligible to participate. Random sampling of the eligible population, stratified by case-control status only, was used to select individuals for participation, using random numbers generated using Stata 13 (49).

Questionnaire distribution

Paper questionnaires were posted to participants in August 2015, accompanied by an invitation letter which was one page in length (50), a Patient Information Sheet (PIS), and a stamped return envelope. The following approaches were employed to increase response rate, supported by evidence from a Cochrane systematic review (43):

- The letters accompanying the questionnaire were personalised (OR of personalised letter versus non-personalised 1.14; 95% CI 1.07 to 1.22, I-squared 63%) (43).
- Stamped return envelopes were used, as opposed to franked return envelopes (OR 1.24; 95% CI 1.14 to 1.35, I-squared 69%) (43).

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- Non-respondents were sent a second copy of the questionnaire (OR 1.41; 95% CI 1.02 to 1.94) (43).

In addition, the invitation letter was signed using a scanned signature by the potential participant's consultant nephrologist. Weak evidence suggests this may increase the likelihood of response (OR for more senior or well-known person vs less 1.13; 95% CI 0.95-1.35) (51). Brown envelopes were used (OR brown vs white 1.52; 95% CI 0.67-3.44) (51, 52), and the primary investigator's contact details were provided in case of any questions (53).

Non-responders were sent a second questionnaire after 4 weeks. A consent form formed the first page of the questionnaire, including the request to link the questionnaire information to information in the participant's renal medical records (e.g. postcode in order to derive an IMD score, renal diagnosis, and history of RRT).

Data collection

Study data were collected and managed using REDCap electronic data capture tools hosted at the University of Bristol (54). REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies.

Data analysis and statistical methods

Findings from this study were required to inform a sample size calculation for a full-scale study, by providing data on frequency of exposures, and variable distribution. Basic statistical analysis was performed to explore the associations between the potential intermediaries (e.g. size of potential donor pool, level of social support, level of patient activation) and case-control (transplant type) status by simple cross-tabulations and mean differences. Medians and inter-quartile ranges were

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2 calculated for continuous variables. Chi-squared, Fisher's exact, and a nonparametric k-sample
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4 test on the equality of medians were used to compare baseline characteristics.
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7 The statistical analysis planned for the full-scale study will more formally quantify the associations
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9 using multivariable logistic regression analysis (OR, 95% CI, p-value). The full-scale study will
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11 examine how SED, either as an individual or composite variable, predicts case-control status. Using
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13 mediation analysis, we will test whether conditioning on the intermediaries attenuates the
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15 observed association between SED and case-control status either partially or completely using
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17 multivariable logistic regression. In addition we will also test for interactions between SED and the
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19 exposure variables, to examine if the relationship between the potential intermediaries and
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21 outcome varies by SED in the larger study.
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25 26 27 **RESULTS**

28
29 Questionnaires were posted to 60 potential study participants. 63% (n=38) of those invited
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31 returned questionnaires. 35 individuals responded to the first questionnaire, and 3 responded to
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33 reminders. 70% (n=21) of invited LDKT recipients and 57% (n=17) of invited DDKT recipients
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35 responded (Table 1: Participant characteristics). Reasons for non-response were not explored for
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37 ethical reasons, but non-respondent characteristics were analysed. Along with DDKT recipients,
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39 men, individuals aged 20-39 and individuals from areas in IMD quintiles 4 and 5 were less likely to
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41 respond (Table 2: Participants and Non-participants). Every participant consented to linkage of the
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43 questionnaire data to information from their medical records.
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Table 1: Participant characteristics

	Cases Live-donor kidney transplant recipients n=21	Controls Deceased-donor kidney transplant recipients n=17
Sex (%)		
Women	12 (57)	11 (65)
Men	9 (43)	6 (35)
Age category (%)		
20-39	5 (24)	1 (6)
40-59	5 (24)	11 (65)
60-79	11 (52)	5 (29)
Ethnicity (%)		
White	18 (86)	15 (88)
Other	3 (14)	1 (6)
IMD quintile (%)		
1 (Least deprived)	6 (29)	6 (35)
2	3 (14)	6 (35)
3	7 (33)	4 (24)
4	4 (19)	0
5 (Most deprived)	1 (5)	1 (6)
Mean number of potential family donors (SD)	14 (12)	14 (12)
Median number of potential family donors (IQR)	11 (13)	11 (7)
Mean PAM score (SD)	64.2 (12.4)	64.5 (15.5)
Median PAM score (IQR)	67.8 (19.4)	60.6 (24.1)
% PAM level 4 (95% CI)	38 (15-61)	35 (10-61)
Mean social support score (SD)	30.0 (6.0)	29.6 (5.3)
Median social support score (IQR)	31.0 (7.0)	30.5 (9.0)
Mean live-donation transplant knowledge score (SD)	6.7 (SD 1.8)	4.9 (SD 2.1)
Median live-donation transplant knowledge score (IQR)	7.0 (2.0)	5.0 (2.0)

SD-standard deviation; IQR-inter-quartile range; CI-confidence interval

Table 2: Participants and Non-participants

	Participants n=38 (% invited)	Non-participants n=22 (% invited)
Sex		
Women	23 (77)	7 (23)
Men	15 (50)	15 (50)
Age category		
20-39	6 (43)	8 (57)
40-59	16 (62)	10 (38)
60-79	16 (80)	4 (2)
Ethnicity		
White	34 (62)	21 (38)
Other	4 (80)	1 (20)
Renal Transplant type		
Live-donor	21 (70)	9 (30)
Deceased-donor	17 (57)	13 (43)
IMD quintile		
1 (Least deprived)	12 (67)	6 (33)
2	9 (75)	3 (25)
3	11 (61)	7 (39)
4	4 (57)	3 (43)
5 (Most deprived)	2 (40)	3 (60)

Missing data

100% of the questions on transplant knowledge, transplant beliefs, social support and patient activation were completed. Three of the nine individuals who had received pre-emptive transplants, and therefore had not received any form of dialysis, did not answer the questions on preparation for dialysis, which suggests that dialysis options weren't considered for back-up if the transplant didn't go ahead, as suggested by one of the cognitive interviewees.

There was a large amount of missing data for the question on income, suggesting that these questions were less acceptable to participants. This was also highlighted in the cognitive interviewing. 16 (42%) selected 'would rather not answer' on the income question. These participants represented all IMD quintiles so it cannot be assumed non-disclosure represents a low

1 or a high income. Three individuals declined to disclose their education history, two preferred not
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4 to disclose their employment status, and one chose not to disclose their housing tenure status.
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9 10 **Transplant preference**

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13 Participants were asked to recall if they had a preference for a certain transplant type prior to
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15 receiving a transplant. Prior to transplantation, the preferences of eventual LDKT and DDKT
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17 recipients differed significantly ($p=0.05$). 57% of eventual LDKT recipients stated that a living-
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19 donor transplant was their preferred transplant type, with the majority favouring a 'known donor',
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21 as compared to 18% of eventual DDKT recipients. The majority (65%) of eventual DDKT recipients
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23 expressed that they had had no preference between a DDKT and a LDKT. After transplantation the
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25 preferences of LDKT and DDKT recipients remained significantly different ($p=0.02$). 62% of LDKT
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27 recipients continued to prefer a LDKT as compared to 6% of DDKT recipients. The majority (71%) of
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29 DDKT recipients still expressed no preference between LDKT and DDKT after transplantation.
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35 The most useful sources of information on RRT were reported as discussions with a health care
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37 professional (97% of participants selected) and written information provided by a hospital (55% of
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39 participants selected).
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43 The mean number of potential related donors available to an individual didn't differ by transplant
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45 type (Table 1) but there was a suggestion of variation with SED (Table 3). More deprived
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47 transplant recipients appeared to report smaller numbers of potential donors than less deprived
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49 transplant recipients. This trend appeared to be statistically significant for cases ($p=0.05$). 58% of
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51 participants had not asked any of their potential donors to consider living kidney donation (52%
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53 LDKT vs 65% DDKT, $p=0.44$).
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Table 3: Median number of potential family donors stratified by socioeconomic deprivation and transplant type

	Cases Live-donor kidney transplant recipients	Controls Deceased-donor kidney transplant recipients
IMD quintile	Median number of potential family donors	Median number of potential family donors
1 (Least deprived)	21	13
2	11	11
3	7	11
4	10	-
5 (Most deprived)	7	8

Live-donor kidney transplantation knowledge and beliefs

There was some evidence of a difference between the R3K-T knowledge score for recipients of LDKTs (Mean 6.7, SD 1.8) and for recipients of DDKTs (Mean 4.9, SD 2.1), $p=0.008$.

The degree of agreement with various belief statements by case-control status is presented in Table 4. With the small pilot sample size, only agreement with one statement differed significantly between LDKT and DDKT recipients. 76.2% of LDKT recipients agreed and 14.3% strongly agreed with the statement 'a live donor kidney transplant may strengthen the relationships between the donor and recipient.' This compared to 41.2% of DDKT recipients agreeing with this statement, with 35.3% being uncertain (p -value = 0.03).

Patient Activation and Social Support

A two-sided t-test was conducted to compare the degree of patient activation, social support and living kidney donation knowledge of LDKT and DDKT recipients. There was no evidence of a difference between PAM-13 score for recipients of LDKTs (Mean 64.2, SD 12.4) and recipients of DDKTs (Mean 64.5, SD 15.5), $p=0.94$. There was no evidence of a difference between the ISEL-12 social support score for LDKT recipients (Mean 30.0, SD 6.0) and DDKT recipients (Mean 29.6, SD 5.3), $p=0.84$.

Table 4: Beliefs about living donation and live-donor kidney transplantation

Belief statement	Transplant type	Strongly disagree %	Disagree %	Agree %	Strongly agree %	Don't know %	Chi2 p-value
It is ethically acceptable to take a kidney from a healthy person.	L	4.8	4.8	61.9	28.6	0	0.56
	D	0	5.9	47.1	47.1	0	
Donors often agree to donate due to feelings of guilt or family pressure.	L	14.3	38.1	14.3	4.8	28.6	0.61
	D	0	47.1	17.7	5.9	29.4	
Donating a kidney is a rewarding experience for the live donors.	L	0	0	66.7	23.8	9.5	0.49
	D	0	0	58.8	17.7	23.5	
Donating a kidney to someone requires an extremely close personal relationship.	L	4.8	61.9	14.3	14.3	4.8	0.50
	D	5.9	35.3	23.5	17.7	17.7	
A live donor kidney transplant may strengthen the relationships between the donor and recipient.	L	4.8	4.8	76.2	14.3	0	0.03
	D	5.9	11.8	41.2	5.9	35.3	
Approaching a potential donor who then says no will change the relationships between the two people.	L	9.5	23.8	33.3	4.8	28.6	0.21
	D	5.9	58.8	11.8	0	23.5	
Asking someone to donate makes the recipient seem selfish or greedy.	L	0	45.0	25.0	20.0	10.0	0.40
	D	0	35.3	35.3	5.9	23.5	
It is acceptable for a parent to receive a kidney from his/her child (over 18 years old).	L	0	4.8	81.0	9.5	4.8	0.25
	D	5.9	11.8	47.1	17.7	17.7	
Decisions about donation should be made by the donor alone. The recipient should not ask for a kidney.	L	4.8	28.6	33.3	28.6	4.8	0.54
	D	0	29.4	47.1	11.8	11.8	
Since the donor operation is not risk free, someone who needs a kidney transplant should wait for a kidney from someone who has died.	L	23.8	66.7	0	0	9.5	0.15
	D	5.9	58.8	0	5.9	29.4	

Logistic regression analysis

The logistic regression analysis was largely performed to demonstrate the planned analysis for the larger study, but findings are presented in Table 5 for illustrative purposes only. The area-level measure of SED, the IMD score, was compared to individual-level measures of SED, including income, education and employment level. With the pilot data, findings were not statistically significant, apart with the model exploring the relationship between income and likelihood of LDKT: in the unadjusted model increasing income was associated with a greater likelihood of having had a LDKT (OR 1.98, 95% CI 1.12-3.50, p=0.02). In the fully adjusted model this relationship persisted (OR 2.15, 95% CI 1.13-4.08, p=0.02). As expected, the IMD score showed a weaker association in the unadjusted model, but after adjustment the OR was similar to that of the employment variable.

Table 5: Odds ratios for the association between being a live-donor kidney transplant recipient and socioeconomic deprivation

Measure of socioeconomic deprivation	Unadjusted model OR [95% CI]	Age, sex and ethnicity adjusted model OR [95% CI]
Index of Multiple Deprivation quintile ^a (n=38)	1.48 [0.82 - 2.64] p=0.19	1.82 [0.90 - 3.69] p=0.10
Income ^b (n=22)	1.98 [1.12 - 3.50] p=0.02	2.15 [1.13 - 4.08] p=0.02
Level of education ^c (n=34)	2.16 [0.98 - 4.76] p=0.06	2.05 [0.88 - 4.79] p=0.10
Level of employment ^d (n=20)	1.65 [0.75 - 3.62] p=0.21	1.75 [0.70 - 4.34] p=0.23

^a OR per increase in IMD quintile

^b OR per £500 increase in monthly household income

^c OR per increase in education level: No formal education/training; Primary school; Secondary school; Vocational/Technical/Trade training; University undergraduate degree; University postgraduate degree

^d OR per increase in level of unemployment (excluding retirees, homemakers and full time education)

DISCUSSION

This study was a pilot of a case-control study which has estimated the important parameters needed to design a future larger main study.

Response rates

The response rate of 63% overall and 70% of invited LDKT recipients is similar to the response rate reported in a published survey of transplant recipients in France (60% response rate) (55). The response rate of 70% from invited LDKT recipients is similar to that of 70.4% of LDKT recipients in the Netherlands who were evaluated using the R3K-T questionnaire (34).

The second mail-out generated 8% of the overall responses and will therefore be repeated in the full-scale study. To further increase response rate, for minimal additional cost, electronic reminders will be sent via text message or email (56). The full-scale study will be based at multiple centres, some of which will serve populations with greater levels of SED than the population served by North Bristol NHS Trust. This should help to increase responses from renal patients in IMD quintiles 4 and 5.

Acceptability of the questionnaire and data linkage

Cognitive interviewing confirmed that the questionnaires were acceptable, with possibly sensitive personal and socioeconomic questions highlighted. Cognitive interviewees suggested that the option of 'would rather not answer' be included for these questions. The good response rate and the overall lack of missing data both suggest that the questionnaires were acceptable.

Almost half of the participants indicated that they would rather not answer a question on income. However the majority were willing to answer other socioeconomic questions, including education,

1
2 employment status, property ownership, and all participants consented to the linkage of the
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4 questionnaire to data stored in the medical records, so IMD scores could be derived from
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7 postcode to generate an area-level measure of the SED experienced by a participant.
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12 13 **Face validity of the content of the questionnaire**

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16 The questionnaire comprised a number of previously validated scales and assessment tools. The
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18 findings of this pilot are in agreement with existing literature: the R3K-T live donation
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20 questionnaire norm-reference score in LDKT recipients has been reported as 6.89 (2.48) (36),
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22 compared to 6.7 in our LDKT cases. This suggests that questions were understood as in previous
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24 studies.
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28 Cognitive interviewing confirmed that the questions were transparent and interpreted as
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30 intended, thus the questionnaire items had good face validity. The low rate of missing data
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32 suggests that questions were apparently understood, with the exception of the questions on
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34 dialysis decision making. It was assumed when developing the questionnaire that all individuals
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36 would have to some extent considered all RRT options, even if they had planned for and received a
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38 pre-emptive transplant. Most recipients of pre-emptive transplants indicated that they had indeed
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40 considered dialysis options, but a few individuals indicated that they hadn't considered dialysis at
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42 all. A filter question will be introduced to the questionnaire in the full-scale study asking if
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44 participants ever considered dialysis.
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51 52 53 **Future research: sample size calculation**

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56 The questionnaire has been designed to measure multiple factors, as detailed above but we have
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58 decided to power a future study on the patient activation variable.
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Based on the distribution of previously observed scores, the '½ Standard Deviation' (½SD) estimate (57) has been suggested as approximating a minimal important difference (MID) for patient reported instruments (57, 58). Empirical evidence from previous studies, physiological arguments, and statistical theory shows a tendency to converge to the ½SD criteria as being meaningful to patients (59).

Using this distribution-based method to estimate a clinically meaningful MID, the pilot study overall mean PAM-13 score's SD was 14, therefore a 7 point difference between cases and controls would be meaningful to detect. This SD is comparable to previously published studies of patient activation (60, 61), including in patients with Chronic Kidney Disease stages 4 and 5 (62). The mean PAM-13 score in our pilot study LDKT cases was 64.2.

To detect a difference of 7 points (½SD) between LDKT cases and DDKT controls (i.e. 64 vs 57) in IMD quintile 5 at 90% power, 5% significance and a 1:1 ratio would require 85 subjects per group (170 total). Therefore to be able to test for a ½ SD difference across all 5 quintiles we need a sample size of 850. We anticipate there were be some missing data so that in the final complete case analysis we may have a reduction of 10% thereby necessitating 944 subjects. In addition, the response 'rate' for the pilot study was 63% (n=38/60) thereby requiring an initial sample size of 1500 participants (750 cases 750 controls) to be approached and hence the need for 4 centres as a minimum. We can detect a far smaller difference (0.16 SD) for a dichotomous exposure or between 6-8% for a categorical outcome.

In order to recruit this study population from individuals transplanted between 2010 and 2015, the full-scale study will have to run at four transplant centres (63). This pilot informed sample size calculation will also allow accurate costing of a full-scale study.

Future statistical analysis plan

In the full-scale study we will initially explore how SED, either as an individual or composite variable, predicts case-control status. We will then test if our potential intermediaries (e.g. size of potential donor pool, level of patient activation) are themselves predicted by case-control status by simple cross-tabulations and mean differences. More formal quantification will be undertaken using logistic regression analysis (OR, 95% CI, p-value). We will then use mediation analysis to test whether conditioning on the intermediaries attenuates the observed association between SED and case-control status either partially or completely using multivariable logistic regression. We will also test for interactions between SED and the exposure variables, to examine if the relationship between the potential intermediaries and outcome varies by SED. For example, we will explore whether poor social support is more important in more deprived patients than less deprived in explaining case-control status.

This pilot study will enable us to run a successful full-scale questionnaire based transplant case-control study, the findings of which will help us better understand how SED is related to the type of transplant an individual receives. This understanding will help us to design and appropriately tailor an intervention to reduce inequitable access to live-donor kidney transplantation.

Contributorship statement

PB conceived of and designed the study, developed the questionnaire, carried out the cognitive interviews, identified the eligible study population, distributed the questionnaires, performed the data analysis and interpretation, wrote the article and approved the submitted version. YBS contributed to study design, provided feedback on the article and approved the submitted

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2 version. CT contributed to study design, provided feedback on the article and approved the
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9 **Competing interests**

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11 The authors declare no conflicts of interest.
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28 of the NHS, the National Institute for Health Research or the Department of Health.
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39 **Data sharing statement**

40 No additional data available.
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Supplementary material – Summary of cognitive interview findings

Four individuals were interviewed, purposefully selected to differ in age, sex, and socioeconomic position (Table 1). Three interviews were conducted in person, whilst one was conducted over the telephone. Individuals were asked to read through the questionnaire whilst thinking aloud, informing the researcher of their opinions on the clarity, intelligibility and simplicity of the question, as well as the ease with which the question could be answered and the suitability of the response options. At the end participants were asked to comment on the overall appearance, layout and length of the questionnaire. The participant and researcher (PB) each had a copy of the questionnaire. Notes were taken by the researcher while the participant worked through the questionnaire.

Table 1: Characteristics of cognitive interviewees

	Cognitive interviewee			
	1	2	3	4
Sex	Male	Male	Female	Female
Age group (years)	60-69 years	30-39 years	60-69 years	30-39 years
Index of Multiple Deprivation (IMD) 2010 decile	10	1	6	7

Across the four interviews the types of dialysis were not universally understood. One participant did not know that there was more than one type of dialysis and required more information to ascertain which type he had received. A simple description of the types of dialysis was therefore added to questions where appropriate.

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3 One participant advised that because they had received a pre-emptive kidney transplant
4 they had not considered dialysis options, and were therefore unable to answer questions on
5 this. After discussion with other participants it was felt that most people should have
6 considered dialysis options even if they planned and received a pre-emptive transplant, and
7 therefore these questions remained.
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12 Regarding the question on potential donors, two interviewees advised that some
13 participants might not know the number of siblings or cousins they have, especially in the
14 context of family breakdown. It was therefore suggested that the option of 'I don't know'
15 was added to this question.
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20 One participant stated that the question 'How many people from the previous table have
21 you communicated with in the last year?' was a difficult question to answer, and asked what
22 the point of the question was. After discussion with the researcher it became clear that the
23 question was aiming to assess the closeness of relationships, but this was assessed
24 separately, and more explicitly, in another question. Therefore the question on
25 communication was removed.
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30 Two participants advised that the section on social support required a time focus. One asked
31 'When is this for? Now or when I was getting my transplant?' Therefore a sentence was
32 added to this section advising that 'When you are answering these questions, please think
33 about your current situation.' This section contained potentially sensitive questions and the
34 researcher specifically explored the acceptability of these questions with participants. All
35 felt that the questions were not too sensitive for them, but suggested that a sentence
36 specifying that a question could be left blank would be a reasonable addition. The addition
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3 of contact details of the researcher if the participants felt they wished to discuss this further
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5 was also suggested.
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8 One interviewee pointed out that one question extracted from a previously published
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10 questionnaire (1) referred to a 'cadaver donor kidney' and that this term is no longer
11
12 acceptable. The term was changed to 'a kidney from someone who has died'.
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16 Finally it was suggested by one participant that all the questions in the section on
17
18 demographics should include a 'Would rather not answer' response option.
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1. Stothers L, Gourlay W, Liu L. Attitudes and predictive factors for live kidney donation: a comparison of live kidney donors versus nondonors. *Kidney Int* 2005 Mar;67(3):1105-11.

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What factors explain the association between socioeconomic deprivation and reduced likelihood of live-donor kidney transplantation? A questionnaire based pilot case-control study

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2 **What factors explain the association between socioeconomic deprivation and reduced**
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4 **likelihood of live-donor kidney transplantation? A questionnaire based pilot case-control study**
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28 **Keywords**

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31 Live-donor kidney transplantation; Socioeconomic inequities; Pilot study
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35 **Word count**

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Abstract

Objectives

Socioeconomically deprived individuals with renal disease are less likely to receive a live-donor kidney transplant than less deprived individuals. This study aimed to develop and pilot a questionnaire designed to determine what factors explain this association.

Design

Questionnaire development and a pilot case-control study. Primary aims were to develop and evaluate a questionnaire, assess response rates and to generate data to inform full-scale study design.

Setting

A UK tertiary renal referral hospital and transplant centre.

Participants

Invited participants comprised 30 live-donor kidney transplant recipients (cases) and 30 deceased-donor kidney transplant recipients (controls). Participants were randomly sampled from all adults who had been transplanted at Southmead Hospital, North Bristol NHS Trust between 1/8/2007 and 31/7/13.

Methods

Participants were posted questionnaires accompanied by an invitation letter from the renal consultant responsible for their care, and a patient information leaflet. Non-responders were sent a second questionnaire after 4-6 weeks. Data was extracted from returned questionnaires and entered onto a REDCap™ database.

Results

1
2 63% (n=38) of those invited returned questionnaires. 16 (42%) declined to answer the question on
3
4 income. 58% of participants had not asked any of their potential donors to consider living kidney
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6 donation (52% LDKT vs 65% DDKT, p=0.44). There was some evidence of a difference between the
7
8 R3K-T knowledge score for recipients of LDKTs (Mean 6.7, SD 1.8) and for recipients of DDKTs
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10 (Mean 4.9, SD 2.1), p=0.008. Variable distribution for the exposure variables of interest were
11
12 determined.
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15 16 17 **Conclusions**

18 Findings from this study will inform a sample size calculation for a full-scale study. The findings of
19
20 the full-scale case-control study will help us better understand how socioeconomic deprivation is
21
22 related to the type of transplant an individual receives. This understanding will help us to design
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24 and appropriately tailor an intervention to reduce inequitable access to live-donor kidney
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29 transplantation.
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Strengths and limitations of this study

- Pilot studies are a key phase of study development and design, essential for evaluating any new research instrument, and for informing the design of a full-scale study.
- The study questionnaire development has been described in detail and the questionnaire evaluated in cognitive interviews.
- The findings of this pilot study will inform a sample size calculation for a full-scale study, by providing data on frequency of exposures, and variable distribution.
- As this is a pilot study it is not designed to be powered to provide evidence for what factors explain the association between socioeconomic deprivation and reduced likelihood of live-donor kidney transplantation.

INTRODUCTION

Live-donor kidney transplantation offers the best treatment in terms of life-expectancy and quality of life (1-6) for many patients with renal failure, and the possible long-term risks of live-donor nephrectomy are small (7-11). In the UK, there are no direct costs to an individual receiving a kidney transplant, and potential donors are entitled to reimbursement from NHS England, including for loss of earnings, travel costs, and additional child care costs (12).

Within the UK socioeconomically deprived individuals are less likely to receive a live-donor kidney transplant (LDKT) (13, 14) compared with less deprived individuals. The same has been demonstrated in the Netherlands (15), the USA (16-18) and Australia (19). Little research exists exploring the reasons for the observed inequity, and a USA Consensus Conference in 2014 on Best Practices in Live Kidney Donation concluded that there is a real need to understand the mechanisms behind these observed disparities and identify targets for intervention (20).

This study follows on from recently published qualitative work (21) in which a series of semi-structured interviews were undertaken with renal patients who had not received a LDKT. These interviews aimed to identify barriers to live-donor kidney transplantation and compared the experiences of individuals from areas of high and low socioeconomic deprivation (SED). Four factors appeared to distinguish more deprived individuals from less deprived: i) Passivity, ii) Disempowerment, iii) Lack of social support, and iv) Short-term focus. In addition to a lack of social support, the emerging themes related to low levels of patient activation, defined as an individual's knowledge, skill, and confidence for managing their health and health care (22, 23). The qualitative interviews were analysed inductively and the work thus generated hypotheses that need further exploration. The questionnaire based case-control study, of which this is a pilot, has been designed to further investigate and validate the qualitative themes, and to quantitatively

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examine the relationships between these variables and the type of transplant received. The qualitative study and subsequent questionnaire represent an 'exploratory sequential mixed methods design' (24) in which elaboration, enhancement, illustration and clarification of the results of one method are sought with the results from the other method (25).

The proposed full-scale study of which this is a pilot has been designed to assess whether SED is associated with:

- i) the number of potential living kidney donors available to a transplant candidate, their suitability and the reasons any were considered unsuitable,
- ii) the social support experienced by a transplant candidate,
- iii) a transplant candidate's beliefs and knowledge about living kidney donation and transplantation, and
- iv) an individual's level of engagement in their healthcare.

The future full-scale case-control study will assess whether each of the variables above may be potential intermediaries in the causal pathway between SED and reduced odds of receiving a LDKT, over a deceased-donor kidney transplant (DDKT). Thus it will examine if the relationship between SED and transplant received is explained by differences in the variables listed above.

The study presented here is a pilot of the proposed case-control study, with the aim of estimating the following important components needed to design the future larger study:

- i) Response rates
- ii) Acceptability of the questionnaires
- iii) Face validity of the content of the questionnaire
- iv) Acceptance rates of linkage of questionnaire information to medical records

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2 v) Logistics, time and costs
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4 Findings from this study were required to inform a sample size calculation for a full-scale study, by
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6 providing data on frequency of exposures, and variable distribution.
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10 11 **METHODS** 12

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14 This questionnaire-based pilot case-control study was a single centre study. Participants were
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16 recruited from Southmead Hospital, North Bristol NHS Trust and data analysis occurred at the
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18 School of Social and Community Medicine, University of Bristol. Ethical approval was provided in
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20 March 2015 by National Research Ethics Service Committee London – Bromley (Research Ethics
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22 Committee reference 15/LO/0435).
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30 **Questionnaire design** 31

32 The overall study development is detailed in Figure 1. The questionnaire was designed and refined
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34 between March 2015 and July 2015. Original item generation was informed by themes arising
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36 from qualitative research (21). A literature review was then undertaken to identify existing and
37
38 validated questionnaires exploring the topics we aimed to investigate. The use of existing
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40 questionnaires and validated measures allows comparison between studies and populations, and
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42 enables possible meta-analysis to be performed.
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49 **Questionnaire content** 50

51 Individuals were asked how many potential donor relatives they had. They were asked whether
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53 any were considered suitable for donation, the reasons donors weren't considered, whether any
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55 donors volunteered, whether any were asked to donate, and whether any donors underwent
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57 assessment for donation.
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Questionnaires also assessed participant demographics, renal replacement therapy (RRT) history, and sources of health information. SED was evaluated at the individual level from education level, employment, income, and housing tenure. It was also evaluated at the area level using a postcode-derived Index of Multiple Deprivation (IMD) score (26, 27). The IMD measure is based on methodology developed at the University of Oxford Social Disadvantage Research Centre (26) and is based on routine census data. Each country in the UK has individual components constituting an IMD score (28). There are seven domains of deprivation (Income, Employment, Health and Disability, Education Skills and Training, Barriers to Housing and Services, Living Environment Deprivation, and Crime) that determine the index score for an area in England, with higher scores indicating greater deprivation. IMD scores are nationally divided into five equal-sized population quintiles according to the level of deprivation of the output area to which they belong, with the fifth quintile representing the greatest deprivation. Therefore, the IMD area-level measure of SED was used as an ecological proxy for individual SED. Both area-level and individual-level socioeconomic variables were collected to allow comparison of the two, as well as to assess the relationship between different aspects/components of SED and health behaviour and outcomes.

Survey tools

The literature review identified the following survey tools which were incorporated into this study's questionnaire:

- Social support was measured using the Interpersonal Support Evaluation List (ISEL) shortened version-12 items survey (29). The 40-item ISEL (30) is one of the most widely used instruments designed to assess perceived social support. The short form measure, ISEL-12 (29) generates a total score that describes overall perceived social support, and three subscales representing perceived availability of appraisal (advice or guidance),

1 belonging (empathy, acceptance, concern), and tangible (help or assistance, such as
2 material or financial aid) social support (29). The ISEL-40 has shown good internal
3 consistency, reliability, test-retest reliability, convergent validity (30, 31) and structural
4 validity (32). The psychometric properties of the ISEL-12 have also been assessed showing
5 good validity and reliability, including in populations similar to our study population in
6 terms of age, ethnicity and gender (33, 34). Construct validity analyses have suggested that
7 ISEL-12 scores are positively related to social network diversity, number of people in one's
8 social network, and life engagement, and inversely related to perceived stress and negative
9 affect (34).

- 10 • Transplant knowledge was measured using the transplant section of the Rotterdam Renal
11 Replacement Knowledge-Test (R3K-T) (35). Prior to the development of this questionnaire,
12 a validated and standardized test of knowledge about kidney disease and all treatment
13 options was not available. This questionnaire was developed and validated in four groups:
14 i) patients on dialysis, ii) patients undergoing LDKTs, iii) the general population of the
15 Netherlands, and iv) the general population of North America. A psychometric analysis was
16 performed using item response theory (36). This study resulted in a questionnaire, the R3K-
17 T, which enables reliable testing of a patient's knowledge on kidney disease and treatment
18 options in clinic and research (37).
- 19 • Transplant beliefs were assessed using questions from a questionnaire from research
20 published by Stothers et al (38, 39). Although not formally validated, the questionnaires
21 were reviewed by three expert focus groups that included physicians, surgeons, nurses,
22 and social workers, and piloted to test reliability. The authors report that test-retest
23 analysis was performed, and there was no evidence of 'skew' or 'halo' effect on any subset
24 of statements (38). No alternative questionnaire for use in this population group could be
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- An individual's level of engagement in their healthcare was measured using Insignia Health's 13 point Patient Activation Measure (PAM) (22, 23, 40). 'Patient activation' is a behavioural concept that incorporates the themes emergent from the qualitative work of passivity, disempowerment and limited knowledge. It is defined as 'an individual's knowledge, skill, and confidence for managing their health and health care.' (22, 23) The PAM was originally developed as a 22 point scale and is validated and highly reliable (41). The 13 point shortened version was subsequently developed to be less burdensome and less costly to administer and complete. The psychometric properties of the shortened version have been assessed (and compared to the 22 point scale) and the measure has been shown to be valid and reliable (22). When the 13-item PAM score is regressed on the 22-item PAM score it accounts for 92% of the variations in the 22-item version estimated activation. Construct validity assessment found that preventive behaviours, disease specific self-management behaviours, and consumeristic behaviours are all strongly correlated with PAM-13 activation scores. The 13 item version has slightly lower reliability for some subgroups, including those with lower income and education, but these lower reliabilities are still within an acceptable range (22).

The PAM is a unidimensional, probabilistic Guttman-like scale (42) that reflects a developmental model of activation. Patient Activation appears to involve four stages: 1) believing the patient role is important, 2) having the confidence and knowledge necessary to take action, 3) actually taking action to maintain and improve one's health, and 4) staying the course even under stress. The measure has good psychometric properties indicating that it can be used at the individual patient level to tailor intervention and assess changes (41). To calculate the total PAM score, the raw score is divided by the number of items answered (excepting non-applicable items) and multiplied by 13. Then, this score is

1 transformed to a scale with a theoretical range 0–100, based on calibration tables, with
2 higher PAM scores indicating higher patient activation. The raw scores can be converted
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4 into four activation levels: 1) (≤ 47.0) not believing activation important, 2) (47.1–55.1) a
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6 lack of knowledge and confidence to take action, 3) (55.2–67.0) beginning to take action
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8 and 4) (≥ 67.1) taking action.
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17 A range of different question response types were used in the questionnaire: numeric, multiple
18 choice, true/false, and scaled, using 4 and 10-point Likert items (43). Likert scaling is a bipolar
19 scaling method which measures either a negative or positive response to a question or statement.
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21 The use of even number scales is sometimes described as a ‘forced choice’ method since the
22 neutral option, which may be selected when a participant is unsure rather than truly neutral, is
23 removed.
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35 **Methods to encourage responses**

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38 In a Cochrane systematic review of methods to increase response rates to questionnaires (44), the
39 following approaches were found to be successful, and for this reason were employed in designing
40 the study questionnaire:
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- 45 - The questionnaire originated from a university (Odds Ratio (OR) of university originated
46 questionnaire versus other 1.32; 95% Confidence Interval (CI) 1.13 to 1.54, I-squared 83%)
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48 (44). Questionnaires and invitation letters were both printed with the University of Bristol’s
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50 logo.
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- The questionnaire content was of importance and interest to participants (OR 2.00; 95% CI 1.32 to 3.04, I-squared 80%) (44), as it explored a disease and treatments that the recipients all had experienced.
- The questionnaire included an assurance of confidentiality (OR 1.33; 95% CI 1.24 to 1.42) (44).
- The questionnaire was short (OR 1.64; 95% CI 1.43 to 1.87, I-squared 91%) (44, 45). The questionnaire was 14 A4 sides of size 12 font. The cognitive interviewees advised that they felt that the questionnaire was short.

Cognitive interviewing

The cognitive interview is a method that can be used 'to evaluate, and to improve, self-report survey questions, measurement instruments, research consent forms, and other written materials.' (46) The cognitive interview involves 'the administration of draft survey questions while collecting additional verbal information about the survey responses, which is used to evaluate the quality of the response or to help determine whether the question is generating the information that its author intends.' (47) Cognitive interviewing was thus undertaken to test each question for clarity, comprehension, face validity, sensitivity, acceptability, as well as the respondent's motivation to answer the question, the ease of retrieval of the required information, and the suitability of response categories. A reparative approach was taken, focussed on improving the quality of survey questions and minimising the risk of response error (46). A summary of the cognitive interview findings is available as supplementary material.

Readability

The questionnaire had a Flesch reading ease measure (48, 49) of 68.3. The higher a Flesch rating, the easier the text is to understand. A score of 68.3 corresponds to text that is written in plain English, in which the average sentence is 15-20 words long, and the average word has two syllables. This reading ease level should be easily understood by 13- to 15-year-old students.

Participant selection

30 LDKT recipients (cases) and 30 DDKT recipients (controls) were selected from all adults (age>18 years) transplanted at Southmead Hospital, North Bristol NHS Trust between 1/8/2007 and 31/7/13. Any individuals identified by their responsible clinician as lacking the mental capacity to consent to study participation according to the Mental Capacity Act 2005, were not eligible to participate. Random sampling of the eligible population, stratified by case-control status only, was used to select individuals for participation, using random numbers generated using Stata 13 (50).

Questionnaire distribution

Paper questionnaires were posted to participants in August 2015, accompanied by an invitation letter which was one page in length (51), a Patient Information Sheet (PIS), and a stamped return envelope. The following approaches were employed to increase response rate, supported by evidence from a Cochrane systematic review (44):

- The letters accompanying the questionnaire were personalised (OR of personalised letter versus non-personalised 1.14; 95% CI 1.07 to 1.22, I-squared 63%) (44).
- Stamped return envelopes were used, as opposed to franked return envelopes (OR 1.24; 95% CI 1.14 to 1.35, I-squared 69%) (44).

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- Non-respondents were sent a second copy of the questionnaire (OR 1.41; 95% CI 1.02 to 1.94) (44).

In addition, the invitation letter was signed using a scanned signature by the potential participant's consultant nephrologist. Weak evidence suggests this may increase the likelihood of response (OR for more senior or well-known person vs less 1.13; 95% CI 0.95-1.35) (52). Brown envelopes were used (OR brown vs white 1.52; 95% CI 0.67-3.44) (52, 53), and the primary investigator's contact details were provided in case of any questions (54).

Non-responders were sent a second questionnaire after 4 weeks. A consent form formed the first page of the questionnaire, including the request to link the questionnaire information to information in the participant's renal medical records (e.g. postcode in order to derive an IMD score, renal diagnosis, and history of RRT).

Data collection

Study data were collected and managed using REDCap electronic data capture tools hosted at the University of Bristol (55). REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies.

Data analysis and statistical methods

Findings from this study were required to inform a sample size calculation for a full-scale study, by providing data on frequency of exposures, and variable distribution. Basic statistical analysis was performed to explore the associations between the potential intermediaries (e.g. size of potential donor pool, level of social support, level of patient activation) and case-control (transplant type) status by simple cross-tabulations and mean differences. Medians and inter-quartile ranges were

1
2 calculated for continuous variables. Chi-squared, Fisher's exact, and a nonparametric k-sample
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4 test on the equality of medians were used to compare baseline characteristics.
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7 The statistical analysis planned for the full-scale study will more formally quantify the associations
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9 using multivariable logistic regression analysis (OR, 95% CI, p-value). The full-scale study will
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11 examine how SED, either as an individual or composite variable, predicts case-control status. Using
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13 mediation analysis, we will test whether conditioning on the intermediaries attenuates the
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15 observed association between SED and case-control status either partially or completely using
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17 multivariable logistic regression. In addition we will also test for interactions between SED and the
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19 exposure variables, to examine if the relationship between the potential intermediaries and
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21 outcome varies by SED in the larger study.
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25 26 27 **RESULTS**

28
29 Questionnaires were posted to 60 potential study participants. 63% (n=38) of those invited
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31 returned questionnaires. 35 individuals responded to the first questionnaire, and 3 responded to
32
33 reminders. 70% (n=21) of invited LDKT recipients and 57% (n=17) of invited DDKT recipients
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35 responded (Table 1: Participant characteristics). Reasons for non-response were not explored for
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37 ethical reasons, but non-respondent characteristics were analysed. Along with DDKT recipients,
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39 men, individuals aged 20-39 and individuals from areas in IMD quintiles 4 and 5 were less likely to
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41 respond (Table 2: Participants and Non-participants). Every participant consented to linkage of the
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43 questionnaire data to information from their medical records.
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Table 1: Participant characteristics

	Cases Live-donor kidney transplant recipients n=21	Controls Deceased-donor kidney transplant recipients n=17
Sex (%)		
Women	12 (57)	11 (65)
Men	9 (43)	6 (35)
Age category (%)		
20-39	5 (24)	1 (6)
40-59	5 (24)	11 (65)
60-79	11 (52)	5 (29)
Ethnicity (%)		
White	18 (86)	15 (88)
Other	3 (14)	1 (6)
IMD quintile (%)		
1 (Least deprived)	6 (29)	6 (35)
2	3 (14)	6 (35)
3	7 (33)	4 (24)
4	4 (19)	0
5 (Most deprived)	1 (5)	1 (6)
Mean number of potential family donors (SD)	14 (12)	14 (12)
Median number of potential family donors (IQR)	11 (13)	11 (7)
Mean PAM score (SD)	64.2 (12.4)	64.5 (15.5)
Median PAM score (IQR)	67.8 (19.4)	60.6 (24.1)
% PAM level 4 (95% CI)	38 (15-61)	35 (10-61)
Mean social support score (SD)	30.0 (6.0)	29.6 (5.3)
Median social support score (IQR)	31.0 (7.0)	30.5 (9.0)
Mean live-donation transplant knowledge score (SD)	6.7 (SD 1.8)	4.9 (SD 2.1)
Median live-donation transplant knowledge score (IQR)	7.0 (2.0)	5.0 (2.0)

SD-standard deviation; IQR-inter-quartile range; CI-confidence interval

Table 2: Participants and Non-participants

	Participants n=38 (% invited)	Non-participants n=22 (% invited)
Sex		
Women	23 (77)	7 (23)
Men	15 (50)	15 (50)
Age category		
20-39	6 (43)	8 (57)
40-59	16 (62)	10 (38)
60-79	16 (80)	4 (2)
Ethnicity		
White	34 (62)	21 (38)
Other	4 (80)	1 (20)
Renal Transplant type		
Live-donor	21 (70)	9 (30)
Deceased-donor	17 (57)	13 (43)
IMD quintile		
1 (Least deprived)	12 (67)	6 (33)
2	9 (75)	3 (25)
3	11 (61)	7 (39)
4	4 (57)	3 (43)
5 (Most deprived)	2 (40)	3 (60)

Missing data

100% of the questions on transplant knowledge, transplant beliefs, social support and patient activation were completed. Three of the nine individuals who had received pre-emptive transplants, and therefore had not received any form of dialysis, did not answer the questions on preparation for dialysis, which suggests that dialysis options weren't considered for back-up if the transplant didn't go ahead, as suggested by one of the cognitive interviewees.

There was a large amount of missing data for the question on income, suggesting that these questions were less acceptable to participants. This was also highlighted in the cognitive interviewing. 16 (42%) selected 'would rather not answer' on the income question. These participants represented all IMD quintiles so it cannot be assumed non-disclosure represents a low

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2 or a high income. Three individuals declined to disclose their education history, two preferred not
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4 to disclose their employment status, and one chose not to disclose their housing tenure status.
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10 **Transplant preference**

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12 Participants were asked to recall if they had a preference for a certain transplant type prior to
13 receiving a transplant. Prior to transplantation, the preferences of eventual LDKT and DDKT
14 recipients differed significantly ($p=0.05$). 57% of eventual LDKT recipients stated that a living-
15 donor transplant was their preferred transplant type, with the majority favouring a 'known donor',
16 as compared to 18% of eventual DDKT recipients. The majority (65%) of eventual DDKT recipients
17 expressed that they had had no preference between a DDKT and a LDKT. After transplantation the
18 preferences of LDKT and DDKT recipients remained significantly different ($p=0.02$). 62% of LDKT
19 recipients continued to prefer a LDKT as compared to 6% of DDKT recipients. The majority (71%) of
20 DDKT recipients still expressed no preference between LDKT and DDKT after transplantation.
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35 The most useful sources of information on RRT were reported as discussions with a health care
36 professional (97% of participants selected) and written information provided by a hospital (55% of
37 participants selected).
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43 The mean number of potential related donors available to an individual didn't differ by transplant
44 type (Table 1) but there was a suggestion of variation with SED (Table 3). More deprived
45 transplant recipients appeared to report smaller numbers of potential donors than less deprived
46 transplant recipients. This trend appeared to be statistically significant for cases ($p=0.05$). 58% of
47 participants had not asked any of their potential donors to consider living kidney donation (52%
48 LDKT vs 65% DDKT, $p=0.44$).
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Table 3: Median number of potential family donors stratified by socioeconomic deprivation and transplant type

	Cases Live-donor kidney transplant recipients	Controls Deceased-donor kidney transplant recipients
IMD quintile	Median number of potential family donors	Median number of potential family donors
1 (Least deprived)	21	13
2	11	11
3	7	11
4	10	-
5 (Most deprived)	7	8

Live-donor kidney transplantation knowledge and beliefs

There was some evidence of a difference between the R3K-T knowledge score for recipients of LDKTs (Mean 6.7, SD 1.8) and for recipients of DDKTs (Mean 4.9, SD 2.1), $p=0.008$.

The degree of agreement with various belief statements by case-control status is presented in Table 4. With the small pilot sample size, only agreement with one statement differed significantly between LDKT and DDKT recipients. 76.2% of LDKT recipients agreed and 14.3% strongly agreed with the statement 'a live donor kidney transplant may strengthen the relationships between the donor and recipient.' This compared to 41.2% of DDKT recipients agreeing with this statement, with 35.3% being uncertain (p -value = 0.03).

Patient Activation and Social Support

A two-sided t-test was conducted to compare the degree of patient activation, social support and living kidney donation knowledge of LDKT and DDKT recipients. There was no evidence of a difference between PAM-13 score for recipients of LDKTs (Mean 64.2, SD 12.4) and recipients of DDKTs (Mean 64.5, SD 15.5), $p=0.94$. There was no evidence of a difference between the ISEL-12 social support score for LDKT recipients (Mean 30.0, SD 6.0) and DDKT recipients (Mean 29.6, SD 5.3), $p=0.84$.

Table 4: Beliefs about living donation and live-donor kidney transplantation

Belief statement	Transplant type	Strongly disagree %	Disagree %	Agree %	Strongly agree %	Don't know %	Chi2 p-value
It is ethically acceptable to take a kidney from a healthy person.	L	4.8	4.8	61.9	28.6	0	0.56
	D	0	5.9	47.1	47.1	0	
Donors often agree to donate due to feelings of guilt or family pressure.	L	14.3	38.1	14.3	4.8	28.6	0.61
	D	0	47.1	17.7	5.9	29.4	
Donating a kidney is a rewarding experience for the live donors.	L	0	0	66.7	23.8	9.5	0.49
	D	0	0	58.8	17.7	23.5	
Donating a kidney to someone requires an extremely close personal relationship.	L	4.8	61.9	14.3	14.3	4.8	0.50
	D	5.9	35.3	23.5	17.7	17.7	
A live donor kidney transplant may strengthen the relationships between the donor and recipient.	L	4.8	4.8	76.2	14.3	0	0.03
	D	5.9	11.8	41.2	5.9	35.3	
Approaching a potential donor who then says no will change the relationships between the two people.	L	9.5	23.8	33.3	4.8	28.6	0.21
	D	5.9	58.8	11.8	0	23.5	
Asking someone to donate makes the recipient seem selfish or greedy.	L	0	45.0	25.0	20.0	10.0	0.40
	D	0	35.3	35.3	5.9	23.5	
It is acceptable for a parent to receive a kidney from his/her child (over 18 years old).	L	0	4.8	81.0	9.5	4.8	0.25
	D	5.9	11.8	47.1	17.7	17.7	
Decisions about donation should be made by the donor alone. The recipient should not ask for a kidney.	L	4.8	28.6	33.3	28.6	4.8	0.54
	D	0	29.4	47.1	11.8	11.8	
Since the donor operation is not risk free, someone who needs a kidney transplant should wait for a kidney from someone who has died.	L	23.8	66.7	0	0	9.5	0.15
	D	5.9	58.8	0	5.9	29.4	

Logistic regression analysis

The logistic regression analysis was largely performed to demonstrate the planned analysis for the larger study, but findings are presented in Table 5 for illustrative purposes only. The area-level measure of SED, the IMD score, was compared to individual-level measures of SED, including income, education and employment level. With the pilot data, findings were not statistically significant, apart from the model exploring the relationship between income and likelihood of LDKT: in the unadjusted model increasing income was associated with a greater likelihood of having had a LDKT (OR 1.98, 95% CI 1.12-3.50, p=0.02). In the fully adjusted model this relationship persisted (OR 2.15, 95% CI 1.13-4.08, p=0.02). As expected, the IMD score showed a weaker association in the unadjusted model, but after adjustment the OR was similar to that of the employment variable.

Table 5: Odds ratios for the association between being a live-donor kidney transplant recipient and socioeconomic deprivation

Measure of socioeconomic deprivation	Unadjusted model OR [95% CI]	Age, sex and ethnicity adjusted model OR [95% CI]
Index of Multiple Deprivation quintile ^a (n=38)	1.48 [0.82 - 2.64] p=0.19	1.82 [0.90 - 3.69] p=0.10
Income ^b (n=22)	1.98 [1.12 - 3.50] p=0.02	2.15 [1.13 - 4.08] p=0.02
Level of education ^c (n=34)	2.16 [0.98 - 4.76] p=0.06	2.05 [0.88 - 4.79] p=0.10
Level of employment ^d (n=20)	1.65 [0.75 - 3.62] p=0.21	1.75 [0.70 - 4.34] p=0.23

^a OR per increase in IMD quintile

^b OR per £500 increase in monthly household income

^c OR per increase in education level: No formal education/training; Primary school; Secondary school; Vocational/Technical/Trade training; University undergraduate degree; University postgraduate degree

^d OR per increase in level of unemployment (excluding retirees, homemakers and full time education)

DISCUSSION

This study was a pilot of a case-control study which has estimated the important parameters needed to design a future larger main study.

Response rates

The response rate of 63% overall and 70% of invited LDKT recipients is similar to the response rate reported in a published survey of transplant recipients in France (60% response rate) (56). The response rate of 70% from invited LDKT recipients is similar to that of 70.4% of LDKT recipients in the Netherlands who were evaluated using the R3K-T questionnaire (35).

The second mail-out generated 8% of the overall responses and will therefore be repeated in the full-scale study. To further increase response rate, for minimal additional cost, electronic reminders will be sent via text message or email (57). The full-scale study will be based at multiple centres, some of which will serve populations with greater levels of SED than the population served by North Bristol NHS Trust. This should help to increase responses from renal patients in IMD quintiles 4 and 5.

Acceptability of the questionnaire and data linkage

Cognitive interviewing confirmed that the questionnaires were acceptable, with possibly sensitive personal and socioeconomic questions highlighted. Cognitive interviewees suggested that the option of 'would rather not answer' be included for these questions. The good response rate and the overall lack of missing data both suggest that the questionnaires were acceptable.

Almost half of the participants indicated that they would rather not answer a question on income. However the majority were willing to answer other socioeconomic questions, including education,

1
2 employment status, property ownership, and all participants consented to the linkage of the
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4 questionnaire to data stored in the medical records, so IMD scores could be derived from
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7 postcode to generate an area-level measure of the SED experienced by a participant.
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12 13 **Face validity of the content of the questionnaire**

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16 The questionnaire comprised a number of previously validated scales and assessment tools. The
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18 findings of this pilot are in agreement with existing literature: the R3K-T live donation
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20 questionnaire norm-reference score in LDKT recipients has been reported as 6.89 (2.48) (37),
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22 compared to 6.7 in our LDKT cases. This suggests that questions were understood as in previous
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24 studies.
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28 Cognitive interviewing confirmed that the questions were transparent and interpreted as
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30 intended, thus the questionnaire items had good face validity. The low rate of missing data
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32 suggests that questions were apparently understood, with the exception of the questions on
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34 dialysis decision making. It was assumed when developing the questionnaire that all individuals
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36 would have to some extent considered all RRT options, even if they had planned for and received a
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38 pre-emptive transplant. Most recipients of pre-emptive transplants indicated that they had indeed
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40 considered dialysis options, but a few individuals indicated that they hadn't considered dialysis at
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42 all. A filter question will be introduced to the questionnaire in the full-scale study asking if
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44 participants ever considered dialysis.
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49 50 **Limitations**

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53 Pilot studies are a key phase of study development and design, essential for evaluating any new
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55 research instrument, and for informing the design of a full-scale study. The study questionnaire
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57 development has been described in detail and the questionnaire evaluated in cognitive interviews.
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2 The findings of this pilot study will inform a sample size calculation for a full-scale study, by
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4 providing data on frequency of exposures, and variable distribution. However, this study has a
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6 couple of limitations. Firstly, the questionnaire was piloted in a transplant centre that serves a
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8 predominantly white British population, and all invited participants spoke English. Although the
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10 questionnaire will be translated if required in the full scale study, the response rate from
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12 individuals whose first language is not English may differ to that from in this study. A second
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14 limitation of this study is that the questionnaire is to be administered to LDKT and DDKT transplant
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16 recipients, both of whom have experienced transplantation and thus any detected differences in
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18 beliefs and knowledge may reflect this experience and be subject to a range of cognitive biases
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20 including justifying their decision, recall bias, and endowment effects. How important these biases
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22 might be for the interpretation of findings depends on whether a difference is detected in the full
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24 scale study.
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34 **Future research: sample size calculation**

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37 The questionnaire has been designed to measure multiple factors, as detailed above but we have
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39 decided to power a future study on the patient activation variable.
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43 Based on the distribution of previously observed scores, the '½ Standard Deviation' (½SD) estimate
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45 (58) has been suggested as approximating a minimal important difference (MID) for patient
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47 reported instruments (58, 59). Empirical evidence from previous studies, physiological arguments,
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49 and statistical theory shows a tendency to converge to the ½SD criteria as being meaningful to
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51 patients (60).
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55 Using this distribution-based method to estimate a clinically meaningful MID, the pilot study
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57 overall mean PAM-13 score's SD was 14, therefore a 7 point difference between cases and
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controls would be meaningful to detect. This SD is comparable to previously published studies of patient activation (61, 62), including in patients with Chronic Kidney Disease stages 4 and 5 (63).

The mean PAM-13 score in our pilot study LDKT cases was 64.2.

To detect a difference of 7 points ($\frac{1}{2}$ SD) between LDKT cases and DDKT controls (i.e. 64 vs 57) in IMD quintile 5 at 90% power, 5% significance and a 1:1 ratio would require 85 subjects per group (170 total). Therefore to be able to test for a $\frac{1}{2}$ SD difference across all 5 quintiles we need a sample size of 850. We anticipate there were be some missing data so that in the final complete case analysis we may have a reduction of 10% thereby necessitating 944 subjects. In addition, the response 'rate' for the pilot study was 63% (n=38/60) thereby requiring an initial sample size of 1500 participants (750 cases 750 controls) to be approached and hence the need for 4 centres as a minimum. We can detect a far smaller difference (0.16 SD) for a dichotomous exposure or between 6-8% for a categorical outcome.

In order to recruit this study population from individuals transplanted between 2010 and 2015, the full-scale study will have to run at four transplant centres (64). This pilot informed sample size calculation will also allow accurate costing of a full-scale study.

Future statistical analysis plan

In the full-scale study we will initially explore how SED, either as an individual or composite variable, predicts case-control status. We will then test if our potential intermediaries (e.g. size of potential donor pool, level of patient activation) are themselves predicted by case-control status by simple cross-tabulations and mean differences. More formal quantification will be undertaken using logistic regression analysis (OR, 95% CI, p-value). We will then use mediation analysis to test whether conditioning on the intermediaries attenuates the observed association between SED and

1
2 case-control status either partially or completely using multivariable logistic regression. We will
3
4 also test for interactions between SED and the exposure variables, to examine if the relationship
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6 between the potential intermediaries and outcome varies by SED. For example, we will explore
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8 whether poor social support is more important in more deprived patients than less deprived in
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10 explaining case-control status.
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13 14 15 16 17 18 **Future interventions** 19

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21 This pilot study will enable us to run a successful full-scale questionnaire based transplant case-
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23 control study, the findings of which will help us better understand how SED is related to the type
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25 of transplant an individual receives. This understanding will help us to design and appropriately
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27 tailor an intervention to reduce inequitable access to live-donor kidney transplantation. If the
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29 socioeconomic inequity in live-donor kidney transplantation is found to be associated with a lack
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31 of social support, not asking potential donors, low levels of patient activation, or a lack of
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33 knowledge then a number of possible interventions exist, that could be targeted at those most
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35 likely to benefit. These include the use of transplant candidate advocates (65) who are individuals
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37 who advocate for a renal patient suitable for transplantation, discussing living donation with
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39 potential donors on the transplant candidate's behalf. Transplant candidate advocates may mean
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41 that people who a transplant candidate had perceived as not offering social support and not being
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43 willing to donate do come forward to undergo evaluation. Patient empowerment interventions
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45 designed to increase patient activation include tailored coaching (66), counselling with information
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47 sheets (67, 68), and support preparing questions for a consultation (69). The findings of the full
48
49 scale study are essential to ensure the right intervention is developed and trialled, targeted at
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51 those most likely to benefit.
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Contributorship statement

PB conceived of and designed the study, developed the questionnaire, carried out the cognitive interviews, identified the eligible study population, distributed the questionnaires, performed the data analysis and interpretation, wrote the article and approved the submitted version. YBS contributed to study design, provided feedback on the article and approved the submitted version. CT contributed to study design, provided feedback on the article and approved the submitted version.

Competing interests

The authors declare no conflicts of interest.

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Data sharing statement

No additional data available.

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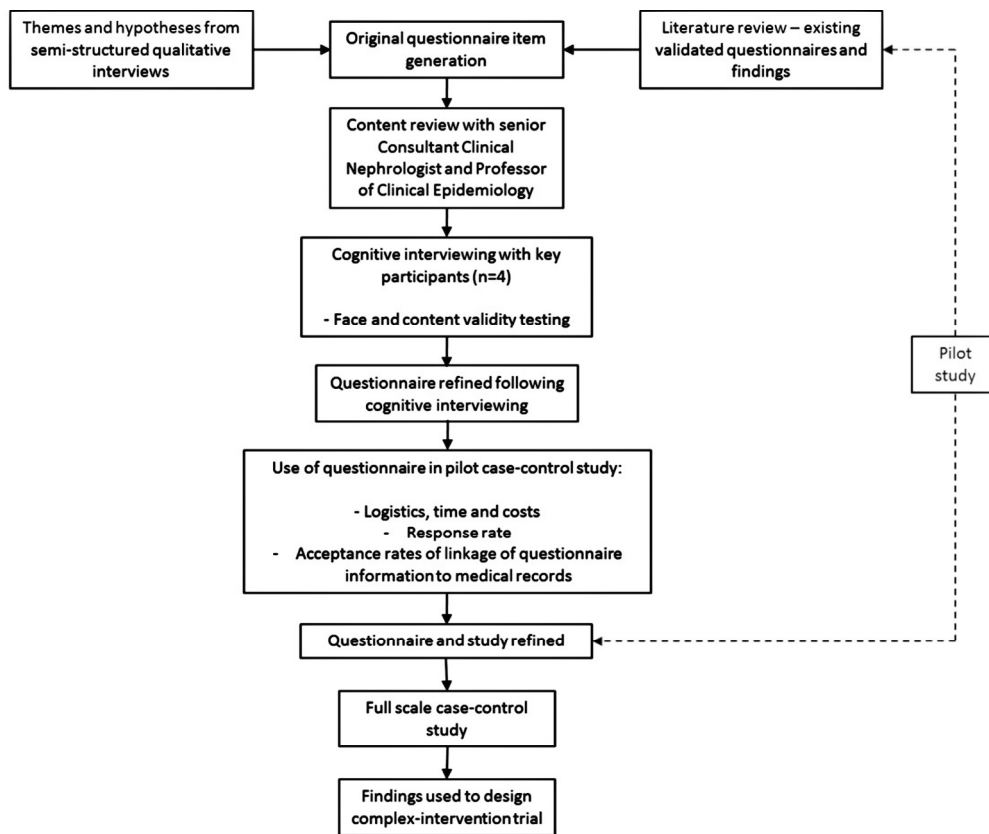


Figure 1 - Research study and questionnaire development
187x157mm (300 x 300 DPI)

Supplementary material – Summary of cognitive interview findings

Four individuals were interviewed, purposefully selected to differ in age, sex, and socioeconomic position (Table 1). Three interviews were conducted in person, whilst one was conducted over the telephone. Individuals were asked to read through the questionnaire whilst thinking aloud, informing the researcher of their opinions on the clarity, intelligibility and simplicity of the question, as well as the ease with which the question could be answered and the suitability of the response options. At the end participants were asked to comment on the overall appearance, layout and length of the questionnaire. The participant and researcher (PB) each had a copy of the questionnaire. Notes were taken by the researcher while the participant worked through the questionnaire.

Table 1: Characteristics of cognitive interviewees

	Cognitive interviewee			
	1	2	3	4
Sex	Male	Male	Female	Female
Age group (years)	60-69 years	30-39 years	60-69 years	30-39 years
Index of Multiple Deprivation (IMD) 2010 decile	10	1	6	7

Across the four interviews the types of dialysis were not universally understood. One participant did not know that there was more than one type of dialysis and required more information to ascertain which type he had received. A simple description of the types of dialysis was therefore added to questions where appropriate.

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3 One participant advised that because they had received a pre-emptive kidney transplant
4 they had not considered dialysis options, and were therefore unable to answer questions on
5 this. After discussion with other participants it was felt that most people should have
6 considered dialysis options even if they planned and received a pre-emptive transplant, and
7 therefore these questions remained.
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16 Regarding the question on potential donors, two interviewees advised that some
17 participants might not know the number of siblings or cousins they have, especially in the
18 context of family breakdown. It was therefore suggested that the option of 'I don't know'
19 was added to this question.
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27 One participant stated that the question 'How many people from the previous table have
28 you communicated with in the last year?' was a difficult question to answer, and asked what
29 the point of the question was. After discussion with the researcher it became clear that the
30 question was aiming to assess the closeness of relationships, but this was assessed
31 separately, and more explicitly, in another question. Therefore the question on
32 communication was removed.
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43 Two participants advised that the section on social support required a time focus. One asked
44 'When is this for? Now or when I was getting my transplant?' Therefore a sentence was
45 added to this section advising that 'When you are answering these questions, please think
46 about your current situation.' This section contained potentially sensitive questions and the
47 researcher specifically explored the acceptability of these questions with participants. All
48 felt that the questions were not too sensitive for them, but suggested that a sentence
49 specifying that a question could be left blank would be a reasonable addition. The addition
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3 of contact details of the researcher if the participants felt they wished to discuss this further
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5 was also suggested.
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9 One interviewee pointed out that one question extracted from a previously published
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11 questionnaire (1) referred to a 'cadaver donor kidney' and that this term is no longer
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13 acceptable. The term was changed to 'a kidney from someone who has died'.
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17 Finally it was suggested by one participant that all the questions in the section on
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19 demographics should include a 'Would rather not answer' response option.
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22 23 24 25 26 **References**

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31 a comparison of live kidney donors versus nondonors. *Kidney Int* 2005 Mar;67(3):1105-11.
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