

The IN-FAKT study protocol: INvestigating the experiences and management of individuals with FAiling Kidney Transplants

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The IN-FAKT Study Protocol: Investigating the Experiences and Management of Individuals With Failing Kidney Transplants

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Abstract

Background: In the UK 1500 kidney transplants fail each year. 2% of living-donor transplants and 5% of deceased-donor transplants fail within a year of transplantation. Many decisions need to be made when a kidney transplant fails, including whether the transplant should be removed, and which immunosuppression medication should be stopped. There is limited evidence on which to base these decisions. We do not understand how decisions are made in the absence of good evidence, and there is national variation in practice. **Aims:** The overall aim is to develop a theory of patient and clinician transplant failure behaviours and decisions that will inform the design of a Randomised Controlled Trial (RCT) to evaluate treatments to optimise the management of transplant failure and improve outcomes for patients and their families. **Methods:** In a UK setting, we will develop a Constructivist Grounded theory using in-depth interviews with people over 18 years who are or have experienced kidney transplant failure, their families/close friends, and renal healthcare professional. Iterative purposive sampling of patients from different hospitals will be undertaken to achieve diversity with respect to age, sex, ethnicity, socioeconomic position, transplant type, and cause of transplant failure. Subsequent sampling will be theoretical, to test and develop hypotheses and theories being constructed. The sample size will be determined by reaching theoretical theme saturation with an anticipated minimum of 25–30 patients, 25–30 family members/close friends and 10–15 renal healthcare professionals. The research team will take a reflexive approach to make any influences or potential biases transparent. This knowledge will be used to develop the programme theory and design an RCT to evaluate treatments delivered at the right time in a patient's journey, to improve experiences and outcomes for people with failing kidney transplants.

Keywords

transplantation, kidney transplants, transplant failure, patient experiences, qualitative, grounded theory

Background

A kidney transplant is described as failing if the function is declining and it is anticipated that the person with the transplant will require alternative treatment (e.g., dialysis) within 6–12 months ([Management of the Failing Kidney Transplant, 2014](#)). A kidney transplant has failed when this alternative treatment has started: this is usually when the kidney function is <10% (eGFR <10 mL/min/1.73 m²).

In the USA, 20% of patients will experience kidney transplant failure within 5 years of transplantation, and over 50% will experience transplant loss by 10 years ([Saran et al., 2019](#)). In the UK, 20% of living-donor transplants and 25% of

deceased-donor transplants have failed by 10 years after transplant ([NHS Blood and Transplant, 2022](#)). In the UK 1500

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kidney transplants fail each year. 2% of living-donor transplants and 5% of deceased-donor transplants fail within a year of transplantation (NHS Blood and Transplant, 2022).

Transplant failure is associated with a high burden of medical morbidity: the international Dialysis Outcomes and Practice Patterns Study (DOPPS) provided evidence that patients with failed transplants fare worse than those with failure of their own kidneys only across traditional measures of quality of care (e.g., anaemia management) (Perl et al., 2012). Individuals with failed transplants experience a higher risk of hospitalization, particularly from infections, low physical functioning, a higher burden of depression and lower quality-of-life (Perl et al., 2012).

Re-transplantation after a transplant has failed offers a lower mortality compared with dialysis (Marcén & Teruel, 2008; Coupel et al., 2003). Pre-emptive transplantation (before someone's kidney function gets to the level at which dialysis is required) is the best treatment in terms of quality of life and life-expectancy for people with advanced kidney disease. Data for the UK have not been reported but in the USA, individuals with failing transplants are less likely to be placed on the waiting list pre-emptively than people with kidney disease of their own kidneys (Schold et al., 2020). This is despite having navigated the system for their first transplant and having a relationship with a transplant unit.

There are several decisions to make at the time of transplant failure: Should the patient be managed in a transplant clinic or a general 'low function' clinic? Should the transplant immunosuppression be continued or withdrawn? Should certain immunosuppression medication (e.g., calcineurin inhibitors) be withdrawn but others (e.g., anti-proliferative agents) continued? Should the transplant remain in-situ or be removed? When should the patient be listed for re-transplantation?

There is limited evidence to inform this decision-making. The evidence gaps regarding management of failing kidney transplants has been highlighted in a recent Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference (Kidney Disease: Improving Global Outcomes (KDIGO), 2022). The 2022 KDIGO Conference on 'Challenges in Management of the Kidney Allograft: From Decline to Failure' highlighted key unanswered questions regarding immunosuppression management, transplant nephrectomy, and care pathways. The British Transplantation Society (BTS) guidelines 'Management of the Failing Kidney Transplant' are largely suggestions (Level 2) rather than recommendations (Level 1) and are based on 'low' (Grade C) and 'very low' (Grade D) quality evidence. Management decisions are therefore being made in the absence of good evidence and the area has been identified as one requiring international research attention (Davis & Mohan, 2021; Knight et al., 2016). The guidelines make the following suggestions:

- Patients are managed by a low kidney function multi-disciplinary team rather than a transplant team alone (2C)

- Immunosuppression is reduced when the graft is failing (2C). However, whilst reducing immunosuppression may reduce risks of infection it is likely to be associated with the production of Human Leukocyte Antigen (HLA) antibodies against the kidney transplant HLA antigens. The guidelines therefore also advise that consideration needs to be given to the relative risk of maintaining current immunosuppression and re-listing for a repeat kidney transplant versus the benefit of immunosuppression withdrawal and the risk of developing HLA antibodies that may preclude options for future kidney transplantation (1D).
- Decisions on whether to remove a failed or failing transplant are made on perceived benefits and risks on a case-by-case basis (2B).

Study Justification

Kidney transplant failure is associated with a high burden of medical and psychological morbidity (Perl et al., 2012), a high risk of mortality (Kabani et al., 2014; Rao et al., 2007) and poor quality of life (Perl et al., 2012). Management of people with failing transplants is informed by limited research and in particular qualitative research and research from the UK are lacking. The area has been identified as one requiring international research prioritisation (Davis & Mohan, 2021; Knight et al., 2016). This project aims to address the described gaps in evidence regarding the optimal management of transplant failure. This study forms preliminary work required to design and deliver a much-needed randomised controlled trial (RCT) to evaluate different management interventions for this clinical problem.

A preliminary scoping review in preparation for this study identified three qualitative studies that had examined kidney transplant failure; two semi-structured interview studies (Gill & Lowes, 2014; Ouellette et al., 2009) ($n = 31$ patients) and one longitudinal case study (Gill & Lowes, 2009). Several other qualitative studies have reported that transplant recipients experience a fear of transplant failure (Nilsson et al., 2008; Jamieson et al., 2016) but not investigated the experiences of those whose transplants have failed. There is currently insufficient primary qualitative research to conduct a meaningful qualitative evidence synthesis.

Previous qualitative research from the UK includes a qualitative longitudinal interview study with 8 patients and 8 'significant others' (13). This found that transplant failure had a devastating impact on all participants, regardless of time of failure since transplantation and resulted in feelings of shock, grief, loss, anger, guilt and depression. Subsequent dialysis treatment was found to be disruptive and served as a constant reminder of transplant failure and a loss of freedom. Participants felt their losses were not recognised by healthcare practitioners and information concerning the prospect of transplant failure and support after failure could be improved (Gill & Lowes, 2014). However, this was a small study and the

age of patient participants ranged from 34–68 years. Experiences and findings may not represent the younger and older transplant recipients. The study was also undertaken 1 year after transplant failure, and may not represent experiences of those whose transplant is failing, or provide evidence of the longer-term consequences of transplant failure (Gill & Lowes, 2014).

Finally, previous single-centre reports suggest that people whose transplants are failing are managed differently across the UK: some renal units run specialist transplant low kidney function (low clearance) services (Arshad et al., 2019) while others manage people with failing transplants in generic low kidney function clinics (for all individuals considering treatments for kidney failure) (Evans et al., 2018), or in transplant clinics. It is not known which model of care results in the best patient experiences and outcomes.

As summarised, there is no research to understand whether, how and when patients want to be prepared for transplant failure, what patient priorities are when their transplant is failing, their understanding of the treatment options, their treatment preferences, their preferred model of care, and their involvement in decision-making. Nor is there research to understand how clinicians and patients conceptualise uncertainty and equipoise regarding transplant failure management, and their willingness to randomise or be randomised to a clinical trial. This study is designed to address these gaps in our understanding and theorisation of the problem. This knowledge is needed to develop the theory and design an RCT to evaluate treatments delivered at the right time in a patient's journey, to improve experiences and outcomes for people with failing kidney transplants. The goal is to use findings from this study to design an RCT of different treatment strategies for kidney transplant failure. Several treatments may be able to be compared in the same RCT in a factorial or platform trial designs. A successful RCT relies on clinical equipoise and positive clinician and patient support for recruitment and randomisation processes. Ultimately findings from the whole programme of research will inform clinical practice guidelines (Tong et al., 2013).

Explanation and Justification of Method

Little is known about how decisions regarding care for failing transplants are made between patients, their families and clinicians in the UK. A previous systematic review and thematic synthesis of qualitative studies (Morton et al., 2010) investigating the views of patients and carers found that decision-making for treatment for chronic kidney disease is influenced by the experiences of other patients and their social context (their lifestyle and family influences). Decision-making when a transplant has failed is therefore likely to be influenced by the individual's own prior experiences of different treatments as well as their social context. Therefore, an ontologically 'subjective' and epistemologically 'interpretivist' research approach is

appropriate. Qualitative research can systematically uncover insights into patient, family member and clinician perspectives and attitudes that shape their decisions and behaviours, which they may not readily express in the clinical setting (Giacomini & Cook, 2000). Ontologically relativist and epistemologically subjectivist, Constructivist Grounded Theory rejects notions of emergence and objectivity (Mills et al., 2006). Philosophically, Constructivist Grounded Theory acknowledges multiple realities, knowledge that is contextual and always incomplete, and the unique subjective positions of the researcher and participant (Charmaz et al., 2018). Qualitative research taking a Constructivist Grounded Theory methodological approach (Charmaz, 2006), using in-depth interviews, will enable the process of decision-making to be investigated in depth and the experiences and perceptions of patients and clinical staff to be analysed within the unique socio-historic context of each individual and their family. We will use Grounded Theory methods to explore the phenomena of interest in Table 1.

Research Aims

The overall aim is to develop a theory of patient and clinician transplant failure behaviours and decisions that will inform the design of an RCT to evaluate treatments to optimise the management of transplant failure and improve outcomes for patients and their families.

The study is designed to explore the following research question: How do patients, family members, close friends and renal health care professionals experience, conceptualise and prioritise their treatment options and care when a kidney transplant fails, and what outcomes do they consider important?

The Setting, Perspective, Comparison, Evaluation (SPICE) Framework (Booth, 2006) was used to define the scope of the study and formulate the research question.

Study Design and Setting

This study follows a Constructivist Grounded Theory methodology (Charmaz, 2006). Data collection will be undertaken using in-depth semi-structured interviews. Participants will be invited to participate from 2–6 UK hospitals. Sites will include both transplanting and transplant referral units, and sites that run specialist failing transplant clinics, and units which run general low kidney function clinics. The sites will represent geographical variation.

Eligibility

Inclusion Criteria

UK-resident adults aged ≥ 18 years from the following groups will be eligible:

Table 1. Study Scope Using the SPICE Framework (Booth, 2006).

| | |
|-----------------------|---|
| Setting | Renal Services in the UK |
| Perspectives | People with a failing/failed kidney transplant, family and close friends, renal health care professionals |
| Phenomena of interest | <ul style="list-style-type: none"> Experiences of kidney transplant failure Views, experiences and understanding of treatment options and models of care and associated favourable/less favourable outcomes Factors associated with 'good' and 'bad' outcomes Views and preferences regarding optimal transplant failure management Priorities regarding outcomes following transplant failure Shared decision-making Acceptability of a clinical trial Beliefs, practices and clinical equipoise regarding optimal management, to determine for which treatment comparisons randomisation is likely to be possible |
| Comparison | Patient, family, close friend, healthcare professional perspectives. Practice in different renal services. Equity: age group, disability, sex, gender, marital status, religion, socioeconomic data (education level, employment status, housing tenure), and ethnicity |
| Evaluation | Constant comparison using constructivist grounded theory and theory development |

- Individuals with a failing kidney transplant (as defined earlier) or a transplant that has failed in the last year.
- People who are the family or close friends of individuals who have a failing kidney transplant or one that has failed in the last year.
- Healthcare practitioners (nephrologists, transplant surgeons, transplant nurse specialists, and renal psychologists)

Exclusion Criteria

Individuals who lack the Mental Capacity to consent to participation, as deemed by their usual healthcare team, will not be eligible to participate.

Sampling

We will undertake in-depth semi-structured interviews with an estimated:

- 25–30 patients.
- 25–30 family/close friends
- 10–15 healthcare professionals across four NHS trusts.

Each year in the UK approximately 1500 individuals experience kidney transplant failure. On average this represents 20 patients at each UK renal unit ($n = 71$). A similar number would be expected to experience transplant failure within the next 6–12 months. We plan to base the study at four large UK renal units and carry out interviews over 18 months (eligible population = $40 \times 4 \times 1.5 = 240$). Our anticipated patient sample size is 25–30, which is approximately 13% of the eligible population.

Iterative purposive sampling of patient participants will be undertaken, aiming to achieve diversity in the initial invited sample with respect to the Cochrane Equity Framework's

PROGRESS-Plus characteristics (O'Neill et al., 2014) including age, sex, ethnicity, and socioeconomic position. We will also aim for diversity in type of transplant received, whether the transplant is failing or has failed, the duration of transplant function prior to failure, and the cause of transplant failure. Purposive sampling of healthcare professionals will be undertaken to ensure there is diversity in sex, age, years of experience, ethnicity, and clinical role. Initial sampling will aim to achieve a diverse sample, but subsequent sampling will be theoretical, selecting participants to test and develop hypotheses and theories being constructed (Marshall, 1996). Sampling will be undertaken alongside data analysis as per Constructivist Grounded Theory. The final sample size will be determined by reaching theoretical theme saturation (Tong et al., 2014) but at this stage we anticipate approximately 60–75 study participants.

Recruitment

Recruitment of Patient Participants

Eligible patient participants will be identified by local principal investigators. A list of potentially eligible participants will be generated by the local IT lead at each study site from renal electronic record systems. Eligible individuals will be informed about the study by local collaborators and provided with information leaflets. If they are interested in hearing more, individuals will be invited to complete a form indicating their consent to be contacted by the research team. Posters will also be displayed in outpatient areas.

Recruitment of Family and Close Friend Participants

Family and close friend participants will be recruited via posters in hospital outpatient areas, and through 'snowball sampling' through patient participants. Patient participants

will be given invitation letters, and information leaflets to share with family and friends. These will contain contact details of the researchers, and return-stamped addressed envelope for individuals to indicate an interest in participation. If a patient participant identifies a family member who also wishes to take part, they will be given the opportunity to be interviewed individually or as a dyad.

Recruitment of Healthcare Professional Participants

Healthcare professionals will be eligible if they are practicing in the UK and work in a kidney transplant team. This will include nephrologists, transplant surgeons, transplant nurse specialists, renal psychologists, renal pharmacists and renal social workers. Professionals at each of the 2-6 sites will be invited to participate in person by the Chief Investigator (CI), Principal Investigator or Research Associate, via email. If they are interested in participating they can reply to the email or telephone the research team (contact details provided in the email).

Consent

All participants will be given participant information leaflets prior to consent being requested. Telephone and email contact details of the CI will be provided in the participant information leaflet so that the invited individual can request further information about the study. Written consent (via post or email) will be obtained prior to interview.

Data Collection

Participants will be invited to take part in a single interview conducted by a Research Associate. The following demographic data will be requested: age group, disability, sex, gender, marital status, religion, socioeconomic data (education level, employment status, housing tenure), and ethnicity. This will allow us to determine if we have achieved the intended diversity. It will also allow us to investigate relationships between personal characteristics and experiences of healthcare and views on optimal management and a possible trial.

The interview content will be guided by the use of a flexible topic guide that is consistent with an iterative Grounded Theory approach. The topic guide will evolve over time as the interviewing progresses. All initial topic guides are provided as [Supplementary Material](#).

Interviews will last approximately 1 hour. They will be undertaken over a virtual platform or the telephone.

Patient or family member/close friend participants will be given a £20 voucher for reimbursement for their time.

Participant Withdrawal

Participants can stop the interview at any time and ask to withdraw from the study. Participants will also be able to

withdraw from the study up to 2 weeks after their interview, and, if requested, their interview data deleted. After 2 weeks the interview will have been analysed and so participants will not be able to withdraw their data at this stage. They will be informed of this in the participant information sheet. Contact details for the Research Associate and the CI will be provided in the information leaflet so that participants can withdraw.

Analysis

Interviews will be audio-recorded, transcribed, and analysed using the iterative, inductive, constant comparison method as described in Grounded Theory ([Charmaz, 2006](#); [Miles & Huberman, 1994](#); [Glaser & Strauss, 1967](#); [Glaser, 1978](#)). Anonymised transcripts will be uploaded to NVivo software ([NVivo qualitative data analysis Software; QSR International Pty Ltd, 2018](#)) to facilitate analysis. The Research Associate will first undertake initial line-by-line coding to identify ideas and name concepts of interest. This will be followed by focused coding in which the initial codes are reduced to a set of selected central codes to pursue in subsequent interviews. As coding proceeds in subsequent interviews, the Research Associate will use constant comparison to compare codes and relationships between codes and will group codes together to form categories. Relationships between categories will be identified and the core category or central concept to which all concepts relate will be identified ([Charmaz, 2014](#)). The Research Associate will then undertake theoretical coding in which relationships between categories are investigated to relate the main categories to the core categories and explanatory theory. If relationships between concepts do not maintain consistency, additional analysis will be required. Theoretical sampling will be undertaken alongside coding: this sampling involves recruiting additional participants and collecting data to test the fit of the initially developed theory. The main principle of theoretical sampling is that the categories emerging from analysis, and the researcher's increasing understanding of the developing theory, now direct the sampling. ([Marcén & Teruel, 2008](#); [Coupel et al., 2003](#)). It enhances theoretical saturation, whereby concepts and categories are perceived as complete and ongoing data collection does not elicit additional insights ([Charmaz & Thornberg, 2020](#)). Throughout the analysis literature will be reviewed, and comparisons made between existing theory and the theory generated from the analysis. All transcripts will be coded by the Research Associate undertaking the interviews, and a subset will be independently dual-coded by one of co-investigators who has expertise in qualitative analysis. A Patient Advisory Group (PAG) will assist with interpretation: codes, themes and developing theory will be discussed as analysis progresses. The progressing analysis will be regularly discussed at team meetings and additional longer meetings convened for this purpose. Additional visual methods will be used to further enhance understanding and theory development. For example, matrices and diagramming will be used to

make comparisons within and between participant groups (patients, family/friends, healthcare professionals), allowing the differing perspectives to be compared and contrasted using the steps recommended by Sally Lindsay (Lindsay, 2019). Similarities and differences within and between groups will be described. The final sample size for the qualitative phase will be determined by reaching theme saturation or when sufficient meaning or understanding of a phenomenon of interest has been reached (Tong et al., 2014). Reports for publication will be written with reference to the Consolidated criteria for reporting qualitative studies (COREQ) (Tong et al., 2007).

Risks

No significant risks are posed by participation in this study. There is no physical risk to participants but there may be an emotional impact. The experience of transplant failure for patients and families may have been difficult, and participants may discuss these difficulties, including emotional and relationship difficulties. Prior to participation individuals will have been provided with information about the study in the participant information leaflet. Participants can stop the interview at any time: there will be a distress protocol to sensitively manage participants who may become distressed by sharing aspects of their lived experiences and hopes for the future. The CI will be available to meet to discuss in person or over the telephone if participants find the interviews have raised issues. If individuals do raise unresolved medical, surgical or psychological issues, with consent, these will be fed back to the clinical team. In situations whereby serious concerns for a participant's wellbeing are raised, local safeguarding procedures will be followed.

Rigour

Several strategies will be adopted to ensure qualitative rigour. High-quality Constructivist Grounded Theory necessitates methodological self-consciousness (Charmaz, 2017). This requires strong reflexivity and openness to scrutinizing who the researcher is, why the researcher has chosen the specific topic, methodology and methods, what assumptions have been made, and how these fit with the research objectives (Charmaz & Thornberg, 2020). The research team will write a reflective piece on our positionalities at the start of the project, and will revisit these at data collection, analysis, and generation of themes.

Within a constructivist grounded theory, Charmaz (Charmaz, 2014; Charmaz, 2006) proposes four main criteria for quality research: credibility, originality, resonance, and usefulness. Credibility begins with having sufficient relevant data for asking incisive questions about the data, making systematic comparisons throughout the research process, and developing a thorough analysis. Credibility also requires the methodological self-consciousness described above. Originality can include offering new insights, providing a fresh

conceptualization of a recognized problem, and/or establishing the significance of the analysis. Resonance demonstrates that the researchers have constructed concepts that both represent their research participants' experiences and provide insights to others. Finally, usefulness includes clarifying research participants' understanding of their experiences, forming a foundation for practice and policy applications. Useful qualitative research will contribute to creating new lines of research, as well as revealing pervasive processes and practices (Charmaz & Thornberg, 2020).

The use of NVivo facilitates transparency during analysis as summaries or interpretations can easily be linked back to the raw data. Data from different sources (patients, family, close friends and healthcare professionals) will be compared and contrasted to determine if different findings are observed. In the final report, direct quotes from study participants will be presented to provide evidence of themes, alongside important context relevant to the data, such as information about the participant). Reports will be written with transparency, and with reference to the COREQ reporting guidelines (Tong et al., 2007).

Patient and Public Involvement

Patients, their families and healthcare professionals have identified the management of kidney transplant failure as a Top 10 priority research question in the NIHR funded James Lind Alliance Kidney Transplant Priority Setting Partnership (Knight et al., 2016): *How can we prevent sensitisation (production of antibodies against the transplant) in patients with a failing transplant, to improve their chances of another successful transplant (e.g., removal of the transplant, withdrawal of immunosuppressive medicines or continuation of these medicines?)*.

Dr Alan Hancock and Mr Paul Maxted, patient co-investigators, have commented on the study aims and study design. In addition to the two patient co-applicants, a PAG comprising four PPI contributors will be established. Group participants will include people who have a kidney transplant, people with experience of transplant failure, and the relatives of people who have experience transplant failure.

PPI activity will be led by two co-investigators. The PPI co-leads will:

- Recruit four public contributors to the PAG and work with them to develop support and training needs
- Organise and coordinate PAG meetings, whilst liaising with the Chief Investigator and Study Management Group
- Act as contacts for PPI contributors
- Feedback conclusions of PPI activities to the Study Management Group
- Communicate with PPI contributors study progress, and provide feedback on the impact of PPI activities on the study activity,

- Lead the writing of plain language reports in conjunction with the PAG.

The PAG will be involved in the design and content of study documents (participant information sheet, topic guide), advise on ways to improve recruitment if this proves challenging, contribute to interpretation of study findings, and assist with dissemination.

Full Copies of Interview Schedules

Flexible interview topic guides are provided as Supplementary Material (Patient topic guide, Family/Friend topic guide, Healthcare professional topic guide).

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Professor Jane Noyes is on the Editorial Board of the IJQM.

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Ethics

Before the start of the study, the study plan and documents were reviewed by an NHS Research Ethics Committee (REC) and the Health Research Authority (HRA). HRA and REC approvals were granted on 16th Feb 2023 (Reference 23/WM/0020).

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Supplemental Material

Supplemental material for this article is available online.

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