



# BMJ Open Protocol for the process evaluation of the GOAL trial: investigating how comprehensive geriatric assessment (CGA) improves patient-centred goal attainment in older adults with chronic kidney disease in the outpatient setting

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## ABSTRACT

**Introduction** The GOAL Cluster Randomised Controlled Trial (NCT04538157) is now underway, investigating the impact of comprehensive geriatric assessment (CGA) for frail older people with chronic kidney disease (CKD). The primary outcome is the attainment of patient-identified goals at 3 months, assessed using the goal attainment scaling process. The protocol requires a dedicated process evaluation that will occur alongside the main trial, to investigate issues of implementation, mechanisms of impact and contextual factors that may influence intervention success. This process evaluation will offer novel insights into how and why CGA might be beneficial for frail older adults with CKD and provide guidance when considering how to implement this complex intervention into clinical practice.

**Methods and analysis** This process evaluation protocol follows guidance from the Medical Research Council and published guidance specific for the evaluation of cluster-randomised trials. A mixed methodological approach will be taken using data collected as part of the main trial and data collected specifically for the process evaluation. Recruitment and process data will include site feasibility surveys, screening logs and site issues registers from all sites, and minutes of meetings with intervention and control sites. Redacted CGA letters will be analysed both descriptively and qualitatively. Approximately 60 semistructured interviews will be analysed with a qualitative approach using a reflexive thematic analysis, with both inductive and deductive approaches underpinned by an interpretivist perspective. Qualitative analyses will be reported according to the Consolidated criteria for Reporting Qualitative research guidelines. The Standards for Quality Improvement Reporting Excellence guidelines will also be followed.

**Ethics and dissemination** Ethics approval has been granted through Metro South Human Research Ethics Committee (HREC/2020/QMS/62883). Dissemination will occur through peer-reviewed journals and feedback to trial participants will be facilitated through the central coordinating centre.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is a prespecified, theory-based process evaluation allowing both deductive and inductive analyses of this complex intervention.
- ⇒ The approach is anchored in sound mixed methodology, reflecting both the updated Medical Research Council guidance, as well as other published guidance for process evaluations of cluster randomised controlled trials.
- ⇒ The lead researcher is independent of the main trial team. Furthermore, the analyses will be conducted without knowledge of the main trial outcomes and in a deidentified format. These measures improve objectivity.
- ⇒ Limitations include that the process evaluation plan was not used to inform the trial intervention design and development. It will not feedback on issues identified during the trial. While this reduces risk of bias and maintains objectivity, it limits the scope of the process evaluation to problem-solve implementation difficulties during the trial.

**Trial registration number** NCT04538157.

## INTRODUCTION

As the global population ages, the impacts of frailty, multimorbidity and psychosocial vulnerability accumulate.<sup>1 2</sup> Frail older adults require a holistic, patient-centred approach to care, with a focus on outcomes relevant to their personal circumstances.<sup>3</sup> Comprehensive geriatric assessment (CGA) is an example of such care.<sup>4</sup> It is a multidimensional, multidisciplinary assessment of medical, psychological and functional capabilities of frail older people that links to an integrated and

coordinated care plan to improve function and patient-centred outcomes.<sup>5</sup>

Despite a number of randomised controlled trials (RCT) investigating the impact of CGA in different settings and patient populations, results have been mixed and it has been difficult to show definitive benefit in different contexts.<sup>6</sup> For example, CGA applied in the inpatient setting shows clear benefit by increasing the likelihood of patients remaining alive and in their home at 12 months, whereas evidence of benefit is limited for CGA delivered in the outpatient or postdischarge setting.<sup>6–8</sup> A recent meta-analysis of CGA in both the inpatient and outpatient settings showed mixed benefits, with no impact on length of stay but improvement in quality of life and caregiver burden.<sup>9</sup>

The reason for the differential efficacy of CGA in various settings has been difficult to tease apart with reference to RCT results alone. Comparison of trial analyses has been limited by significant heterogeneity not just in outcome measures, but also in the content and processes of the intervention itself.<sup>7</sup> Furthermore, the details of the intervention are not always clear in the literature. The mixed results seen in the literature likely reflect that CGA is a complex healthcare intervention. Despite the broadly accepted general definition of CGA, the details of intervention characteristics vary significantly between trials. Variations are reflected in components and processes of the intervention, contributions and roles of various healthcare professionals, and different settings and patient groups.<sup>5</sup> CGA is also heavily influenced by context and implementation factors, including but not limited to the people delivering the intervention, processes of change, leadership, and educational and data resources. This means that even if the processes of CGA were delivered uniformly, outcome effects would vary in different trial and clinical contexts. Therefore, it is not enough to know whether CGA might work in certain situations, as RCTs might indicate, but to understand how and why it can be effective in different situations. However, this is generally not possible with reference to the trial output data alone. Rather, it requires an analysis of implementation and process factors, thus supporting translation of trial results into effective policy and clinical practice.<sup>10 11</sup>

A few recent clinical trials of CGA have been supported by dedicated process evaluations, which have improved trial interpretation. For example, a trial of CGA for community-dwelling older adults concluded that participants expressed the need for a holistic view and that the proactive nature of the intervention delivered unexpected help.<sup>12</sup> A trial of perioperative CGA for emergency abdominal surgery, in which CGA did not improve survival or length of stay, was strengthened by a dedicated process evaluation which showed that intervention fidelity in the trial was poor, social aspects of change were challenging and resources were poor.<sup>13</sup> Another process evaluation of a behaviour change intervention for older adults highlighted the importance of assessing the fidelity of a trial intervention. In that trial,

the quality of motivational interviewing and goal-setting was poor, with 90% of goals set having a low potential for behaviour change, and only 1 of 11 motivational interviewing thresholds meeting a quality threshold.<sup>14</sup> Questions remain about what are the key processes without which CGA lacks benefit, including the relative importance of goal-setting, care planning and follow-up. The role of patient and caregiver expectation in shaping outcomes is also poorly understood. Furthermore, there is doubt about how CGA might work in the outpatient setting when delivered primarily by a single clinician rather than a multidisciplinary team.

CGA may be particularly suited to older adults with chronic kidney disease (CKD) who have high degrees of frailty and functional impairment.<sup>15 16</sup> Process evaluations have occurred for the implementation of specific CGA programmes in nephrology care. These have suggested CGA can help anticipate and manage risks, identify problems and focus decision-making to be patient-centred.<sup>17 18</sup> However, a challenge for CGA in this cohort is ensuring that goals and assessments are communicated appropriately to patients. Effective multidisciplinary working has been identified as important in ensuring CGA is beneficial for this group.<sup>19</sup>

### The GOAL trial

The GOAL trial (*Comprehensive Geriatric Assessment for Frail Older People with Chronic Kidney Disease to Increase Attainment of Patient-Identified Goals - A Cluster Randomised Controlled Trial*) is a pragmatic, cluster RCT of CGA for frail older adults with CKD conducted in the outpatient setting. The pragmatic design of the trial means that geriatricians are asked to provide CGA as they usually would in their clinical practice. This is a comprehensive, multidimensional assessment provided by a geriatrician in the outpatient setting. No proforma or structure to the CGA is mandated, and it is at the discretion of the geriatrician to what degree they employ multidisciplinary input or ongoing follow-up. The primary outcome of interest is goal-attainment scaling, with secondary analyses focusing on quality of life as well as clinical and operational outcomes such as readmissions, return to home, mortality and cost-effectiveness. The protocol for the main GOAL trial is published.<sup>20</sup> Recruitment for the GOAL trial concluded in July 2023. On completion of trial recruitment and follow-up, we will be conducting a dedicated process evaluation of the GOAL Trial, focusing on implementation, recruitment, reach, context and causal pathways, as described in this protocol.

The GOAL trial results are much anticipated and will improve our understanding of optimal models of care for people living with frailty and CKD. The trial design is deliberately pragmatic, to optimise the trustworthiness of the results when applied to the non-trial context. However, because the intervention, CGA, is so complex, the main trial data results will be difficult to interpret

without the process evaluation work that sits alongside. The process evaluation will improve understanding of how resources, people, context and causal mechanisms work together in the context of the GOAL trial to augment outcomes. The process evaluation will also improve our understanding of how CGA is experienced by those patients with frailty and CKD who receive the intervention in the outpatient setting. When the GOAL results are available, the next question will be how the results can be translated to health service delivery in an optimal way. The process evaluation analysis will play an important role in closing the know-do gap that so often plagues complex interventions such as CGA.<sup>21</sup>

## METHODS AND ANALYSIS

### Broad aims and design

The aim of the process evaluation is to understand how outpatient CGA might be effective in improving health outcomes for frail older adults with CKD, in the context of a cluster RCT. Our approach incorporates the Medical Research Council (MRC) guidance for developing and evaluating complex interventions published in 2021, and for process evaluation of complex interventions, updated in 2015 from previous guidance published in 2008.<sup>22–24</sup> Specifically, we aim to investigate implementation, mechanisms of impact and context of the CGA intervention. In addition to addressing these MRC domains, we will structure our study design and research questions according to published guidelines for process evaluations of cluster RCTs.<sup>25</sup>

A key objective is an exploration of how CGA was implemented in the trial context, including recruitment processes (who was recruited and how), and how the intervention was delivered to patients. Other key objectives include the exploration of patient response to the intervention and perceived acceptability to patients, unexpected consequences of the intervention and broader contextual factors that influenced implementation and patient experience. The aim is that this exploratory analysis will allow further refinement of programme theory, to understand the impact of contextual factors on causal mechanisms.

The design of the process evaluation incorporates four iterative stages: development of programme theory, generation of research questions, generation of data and analysis of data. The process evaluation will occur without knowledge of trial outcomes. The process evaluation includes key investigators involved in the main GOAL trial. However, the initial analysis will be conducted by one independent researcher, the first author, who is not involved in the main trial and will not feedback results while the trial is ongoing. Furthermore, collection of data specific to the process evaluation, such as semistructured interviews, will only commence once each site has completed the last-patient, last-visit

to limit the process evaluation work influencing the main trial outcomes.

Data collection for the process evaluation will take place between August 2023 and June 2025. Analysis of process data will take place between June 2024 and August 2025.

### Overview of mixed methodology

Data sources and recruitment processes for the process evaluation are presented in figure 1.

The process evaluation will allow for both deductive and inductive approaches, an iterative process to incorporate new learning through ongoing data collection, review and reflection. The process evaluation will predominantly be carried out by three researchers (STF, RH and MJ). One of these (STF) is not involved in the main outcomes trial and has no input into the main trial design, data collection or data analysis. The others (RH and MJ) are investigators in the main outcomes trial. Raw data collection will be carried out by STF. Analysis of qualitative data will be done by STF with contribution from MJ. The qualitative analyses will then be discussed with RH and other team members for the purposes of triangulation. A summary of the data collection methods that will be used to answer the relevant domains of the process evaluation are presented in figure 1 and table 1.

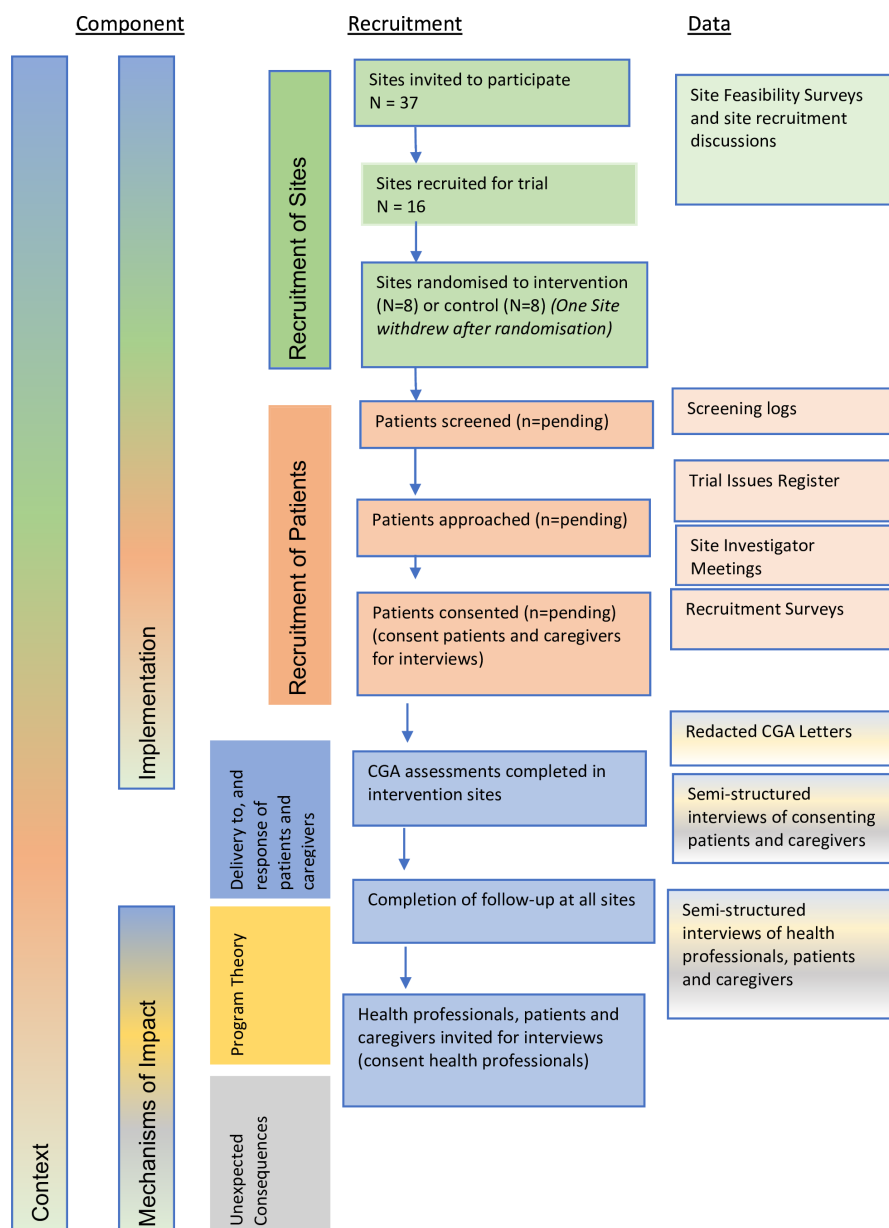
We aim to include all 16 sites where the GOAL trial is conducted in the process evaluation. These are in various locations around Australia, in New South Wales, Queensland, South Australia, Tasmania, Victoria and Western Australia. A mix of inner and outer metropolitan and regional sites will be included, although notably there are no rural locations. This allows consideration to be given to a range of different perspectives, and examination of how varying contextual factors, implementation processes and patient characteristic impact on trial outcomes.

### Development of programme theory

A narrative literature review will be conducted to generate hypotheses about the causal mechanisms at play in the efficacy of CGA and how implementation of CGA might be affected by context to augment outcomes. Through an iterative process of feedback and reflection between the authors, this will lead to the development of a hypothesised programme theory of how CGA might work in the outpatient setting.<sup>24</sup>

In organising our programme theory in such a way that can guide collection of data, we will develop a logic model that accounts for the domains in the MRC Guidance to facilitate data analysis and coding.<sup>23 24</sup> An early version of this logic model is presented in figure 2.

To date, an early programme theory has been developed, which will be further developed. We propose that CGA works through an iterative process of assessment that is holistic and takes account of the 'whole person'. It includes development of a management plan and care coordination, both of which require a person-centred approach, interdisciplinary working and a focus on



**Figure 1** Recruitment for GOAL (*Comprehensive Geriatric Assessment for Frail Older People with Chronic Kidney Disease to Increase Attainment of Patient-Identified Goals - A Cluster Randomised Controlled Trial*) process evaluation. CGA, comprehensive geriatric assessment.

mutually agreed goals of care. CGA works when goals that are personally meaningful to the patient are framed so that a coordinated multidisciplinary management plan, that is, acceptable to the patient, can be organised. The multidisciplinary team, having clear roles and effective working relationships, work with the patient to achieve goals. This means the patient and caregiver perceive value in the intervention and trust the assessments of the multidisciplinary providers. Contextual inputs, such as access to support from the executive, adequate funding, physical resources and knowledge acquisition mean that treatment plans, can be executed with effectiveness. Communication, interprofessionally and between the patient and health professionals, is

clear and effective meaning that all members are 'on the same page'.

### Generation of research questions

The development of the programme theory allowed the generation of research questions that could be tested during the process evaluation. These research questions relate to CGA delivered during the trial as well as broader questions of how CGA might work in varying contexts. The process evaluation will be flexible enough to allow an iterative process of reflection and discussion, so that new learnings offered through the study can reinforce and strengthen the underlying programme theory and allow generation of new research questions. The way in which these research questions link with MRC



**Table 1** Organisation of data collection method to address key questions in process evaluation for CGA in the GOAL (Comprehensive Geriatric Assessment for Frail Older People with Chronic Kidney Disease to Increase Attainment of Patient-Identified Goals - A Cluster Randomised Controlled Trial) trial

Component	Data source	Data collected
<b>Recruitment of clusters: who was recruited and how?</b> MRC domains: Implementation, acceptability, and barriers and enablers	Site meetings <b>Site recruitment surveys</b> Feasibility surveys	What were the characteristics of clusters who agreed to participate and did this suggest any bias? How many of the approached sites (=clusters) agreed to participate? Why (or why not) did sites agree to participate? What were the barriers and enablers? How did COVID-19 impact the site's participation?
<b>Response of clusters: how did clusters change or adapt due to the intervention?</b> MRC domains: Implementation, acceptability, and barriers and enablers	Issues register Site meetings Outcome data including where CGA was intended but not delivered <b>Recruitment surveys</b> <b>Interviews with health professionals</b>	Was there a local clinical trials nurse responsible for the trial? How did sites organise to provide CGA? To what extent was the CGA organised through an MDT? Was there evidence of effective clinical leadership? Were MDT Meetings present? What was the method of communication with the GP? How was communication organised between various stakeholders within sites Where was CGA provided on the sites? Was telehealth delivery used? Was this temporary for the trial?
<b>Recruitment of individuals: which patients were recruited and how?</b> MRC domains: Implementation, acceptability, and barriers and enablers	Screening logs Issues register Site meetings <b>Recruitment surveys</b>	Why did individuals agree to participate? Why not? What were the characteristics of individuals who agreed to participate? Did this suggest any bias? Did patients have trust in CGA, in providers and in the health service
<b>Delivery to individuals: what was delivered to the individual as the CGA intervention?</b> MRC domain: Implementation	Number and characteristics of participants Timing, place, duration and documentation of CGAs <b>Redacted CGAs</b> <b>Interviews of health professionals</b> <b>Interviews of patients and caregivers</b>	What form did the CGA take and what were the CGA components? To what extent was CGA multidimensional? To what extent was there adequate 'dose'? To what extent was the assessment 'structured'? To what degree was a multidisciplinary process employed? Did goal-setting form part of CGA? To what extent was collateral history and multisource feedback included? To what extent did the patients and caregivers agree with the management plan? To what extent was shared decision-making evident? Was goal setting linked to BCT? What was the fidelity with which the behaviour change techniques were implemented? Was there evidence of formulation of a management plan? How was communication structured? How did patients perceive the intervention? How did facilitation of CGA through nephrologists and research nurses change outcomes? What factors facilitate maintenance of CGA within and out of the trial setting? Was effective clinical leadership evident in care coordination? Was care coordination and follow-up present? To what extent was there regular review?

Continued

**Table 1** Continued

Component	Data source	Data collected
<b>Response of individuals and maintenance over time: how did individuals perceive the intervention and how did their behaviour change?</b> MRC domains: Acceptability, and barriers and enablers	<b>Recruitment surveys</b> <b>Interviews of patients and caregivers</b>	Did individual behaviour change after CGA? How acceptable was the intervention? Did patients and caregivers have a view of the health issues and management plan that was congruent with that of the geriatrician? Did CGA foster self-management? Did individuals have trust in the service providers and health service? To what extent were families and caregivers involved?
<b>What are the unintended consequences of the intervention?</b> <b>What unforeseen outcomes of the intervention were observed, both wanted and unwanted?</b> MRC domains: Unintended consequences	<b>Interviews of health professionals</b> <b>Interviews of patients and caregivers</b>	What were the perceived outcomes/effects of CGA that were not expected or monitored in the main trial paper? What are the unintended consequences (good and bad) of providing CGA in the outpatient setting for frail older adults with CKD? What are the perceived barriers and harms of CGA in this setting, and how do these perceptions impact on outcomes?
<b>What theory can explain how CGA works? What are the causal mechanisms at play?</b> MRC domains: casual mechanism, barriers and enablers, and context	<b>Redacted CGAs</b> <b>Interviews of health professionals</b> <b>Interviews of patients and caregivers</b>	What components of CGA were perceived to be of benefit? What were the impediments to positive outcomes from CGA? What components (of the intervention, implementation or context) were associated with positive or negative outcomes? Do the assumptions made about causal mechanisms of how CGA impacts goal attainment add up, with reference to the logic model developed in the initial stage of the research? What are the important aspects which, if left out, undermine the efficacy of the CGA for older adults with CKD?
<b>What is the broader context in which the trial and CGA was delivered?</b> <b>How did context change how the trial was implemented and delivered, and how did this interact with the active components of the intervention to modify the outcome?</b> MRC domains: context, and barriers and enabler	<b>Site meetings</b> <b>Issues register</b> <b>Redacted CGAs</b> <i>Health diaries</i> <i>Interviews of health professionals</i> <i>Interviews of patients and caregivers</i>	To what extent were clusters already providing CGA to these patients? Was there evidence of clinical leadership at an organisation level that influenced the implementation? Were the necessary resources available (time, money human, data systems, transport) to allow the success of CGA? Was there evidence of avenues and processes for communication and information sharing between MDT? Were patients involved in service design? How did the local organisational and health service structure, culture and local relationships impact on implementation and did they interact with causal mechanism to modify outcomes? What are the barriers and enablers to CGA effectiveness in the trial context and how reflective are these of those seen outside of the trial setting? How involved were GPs in the provision of CGA? How was billing/reimbursement structured at the site?

This uses the framework in Grant *et al*<sup>25</sup> and addresses the process evaluation domains set out in the MRC guidance.<sup>24</sup> For the data generation methods, those done as part of the main trial are highlighted in *italics*, whereas those that will be completed specifically for the process evaluation are in **bold italics**.

BCT, behaviour change technique; CGA, comprehensive geriatric assessment; GP, general practitioner; MDT, multidisciplinary team; MRC, Medical Research Council.

Inputs (Context and Resources)	CGA Activities	Outputs	Outcomes
<b>Resources</b> <ul style="list-style-type: none"> <li>- Reliable data systems and AV technology</li> <li>- Available and appropriate clinical space (or ward environment<sup>(6)</sup>)</li> <li>- Availability of appointments</li> <li>- Reliable transport</li> <li>- Interpreting services</li> <li>- Financial resources</li> <li>- Adequate time<sup>(6)</sup></li> <li>- Availability of evidence base protocols for management and prevention of common geriatric conditions<sup>(27)</sup></li> </ul>	<b>1. Holistic Assessment</b> <ul style="list-style-type: none"> <li>- Obtaining collateral history<sup>(31)</sup></li> <li>- Systematic approach to content of CGA<sup>(34)</sup></li> <li>- Systematic approach to whom CGA is targeted towards<sup>(34)</sup></li> <li>- Structured assessment<sup>(6, 30)</sup></li> <li>- Use of standardised assessment tools<sup>(30)</sup></li> <li>- Assessment of goals and aspirations<sup>(31)</sup>, involving patient or caregiver<sup>(6, 29, 30)</sup></li> <li>- Holistic approach to care<sup>(31)</sup></li> <li>- Tailoring domains to the patient<sup>(31, 34)</sup></li> <li>- Identification of the caregiver<sup>(31)</sup></li> </ul>	Multiple sources of collateral history are synthesised into a single comprehensive picture of patients current health status, including vulnerabilities and assets  Articulation of goals that are achievable and relevant  Formulation of a management plan that is person-centred and holistic  Follow-up is scheduled  Implementation of behavioural change techniques  MDT, patient and caregiver have a shared vision of issues, goals and management plan  Care coordination happens through an iterative process involving frequent feedback and open communication  Implementation of medical recommendations of CGA, <sup>(33)</sup>	Improved health <sup>(36)</sup> and wellbeing <sup>(36)</sup> , mental wellbeing <sup>(31)</sup> , quality of life <sup>(31)</sup> , cognitive function <sup>(5)</sup> and independence with ADLs <sup>(5, 31)</sup>  Increased attainment of patients' own goals?  Slowed progression of frailty?  Help people live well with their conditions <sup>(31)</sup>  Welfare of the carer <sup>(31)</sup> and family/carer satisfaction <sup>(27, 29)</sup> and PROMs <sup>(5, 29)</sup>  Reduced mortality <sup>(5)</sup>  Reduced hospital re/admissions <sup>(27, 29)</sup> , length of stay <sup>(27, 31)</sup> , time in ED and wait for surgery <sup>(27)</sup>  Reduced RACF admission <sup>(27)</sup> and more living at home <sup>(5, 31)</sup>  Reduced functional decline <sup>(27)</sup> delirium, pressure sores, incontinence, infections, wound infection, pneumonia, sepsis and restrain use <sup>(27)</sup>  Cost effectiveness <sup>(6)</sup>
<b>Service Design</b> <ul style="list-style-type: none"> <li>- Strong programs of QI and Audit</li> <li>- Ability of health service to accommodate CGA<sup>(28)</sup></li> <li>- Involvement of patients in service design<sup>(29)</sup></li> <li>- Process of selecting patients likely to benefit (older, frail, comorbidities, functional decline, falls). Identification of people who are too well or too unwell and unlikely to benefit<sup>(5, 27, 30-33)</sup></li> <li>- Patients with a high level of frailty<sup>(31)</sup></li> </ul>	<b>2. Care Planning</b> <ul style="list-style-type: none"> <li>- CGA organised through an MDT<sup>(31)</sup></li> <li>- Patient offered chance to be at MDT meeting<sup>(31)</sup></li> <li>- Accommodation of patient and 'caregiver' interpersonal factors to facilitate shared decision making<sup>(30, 36)</sup></li> <li>- Discharge planning<sup>(27)</sup>, with patient and caregiver<sup>(31)</sup></li> <li>- ACP<sup>(27)</sup>, with patient and caregiver<sup>(31)</sup></li> <li>- Tailoring treatment plans to the individual patient<sup>(6)</sup></li> </ul>		
<b>Culture</b> <ul style="list-style-type: none"> <li>- Prioritisation of quality care for older adults</li> </ul>			
<b>Roles and relationships</b> <ul style="list-style-type: none"> <li>- Effective team relationships and team building</li> <li>- Communication with personnel to increase understanding about the effect and perceived benefit of CGA<sup>(28)</sup></li> <li>- Clearly defined roles for all MDT<sup>(27)</sup></li> <li>- Adequate training and supervision<sup>(28)</sup></li> <li>- Appropriate workload of involved professional<sup>(28)</sup></li> <li>- Working conditions of geriatricians<sup>(34)</sup></li> <li>- Clinical leadership<sup>(6)</sup></li> <li>- Multidisciplinary Geriatric medical knowledge, experience and competence<sup>(6, 27, 29-31, 35)</sup></li> <li>- Clinical structure ensures medical recommendations of CGA are implemented<sup>(33)</sup></li> </ul>	<b>3. Care Coordination</b> <ul style="list-style-type: none"> <li>- Daily review available<sup>(27)</sup></li> <li>- Regular MDT meetings<sup>(27, 6)</sup></li> <li>- Facilitating a degree of self management<sup>(36, 37)†</sup></li> <li>- Clear communication<sup>(36)</sup></li> <li>- Iterative process of review<sup>(30)</sup></li> <li>- Involvement of family and caregivers in care<sup>(29)</sup></li> <li>- Involvement of GP<sup>(27, 29)</sup></li> <li>- For inpatients: Engagement of cognitively- and speech-impaired patients; Provision of help if needed; Time out of bed<sup>(37)</sup></li> <li>- Outpatient follow-up<sup>(6, 33)</sup></li> </ul>		

**Figure 2** Logic model of CGA developed from literature review. ACP, advanced care planning; ADL, activities of daily living; AV, audio-visual; CGA, comprehensive geriatric assessment; ED, emergency department; GP, general practitioner; MDT, multidisciplinary team, PROM, patient-reported outcome measure; QI, quality improvement; RACF, residential-aged care facility.

guidance, and how they have led to the specific questions in our evaluation work, are detailed in [table 1](#).<sup>24 25</sup>

## Generation of data

Data will be generated from several sources

Implementation data will be collected after recruitment has closed at each site (ie, last patient, first visit)

1. Recruitment discussions: Minutes of site meetings and recruitment discussions, by trial staff will be analysed. These minutes will be recorded by the central coordinating centre during the trial and will not be transcribed by the process evaluation teams. A list of factors that facilitate or hinder recruitment will be documented. Difficulties that sites encounter recruiting individuals will also be discussed and recorded in regular meetings between sites and the clinical trial team. All data will be analysed and presented in a deidentified format.
2. Feasibility surveys were conducted by sites prior to being recruited to the trial. No identifying data will be shared or included in the analysis.
3. Recruitment survey: Principal investigators and research coordinators will be sent a survey about processes, facilitators and challenges with patient recruitment. This will be used in conjunction with interviews (below) to assess recruitment processes but will only be analysed and presented in a deidentified format. A copy of the recruitment surveys for principal investi-

gators and research coordinators is available as online supplemental appendices A and B.

4. Screening logs: These are kept by the research coordinators and include information such as a number of patients screened, approached and enrolled. They will be analysed in a deidentified format.
5. Trial issues register: This is kept by the central coordinating centre as a summary of all process issues identified during the trial. This will include issues related to recruitment, trial fidelity, communication issues, unintended consequences and barriers and enablers to the implementation of CGA at the site.

## Redacted CGA letters

Intervention sites will provide written records of five CGA medical letters (per site), with redaction of identifying data. These will be convenience sampled. They will be analysed descriptively, using manual content analysis to extract the key domains assessed, multidisciplinary involvement and other key components such as goal-setting and follow-up. They will also be analysed qualitatively, to explore how geriatricians described the identified issues, patient goals and patient concerns, using a reflexive thematic analysis.<sup>26 27</sup>

## Semistructured interviews with purposively sampled patients and their caregivers, and selected health professionals involved in the GOAL trial

1. Sampling and sample size: We will purposively sample health professionals, patients and caregivers for



semistructured interviews. Interviewers of health professionals and patients will be conducted separately. All patients and caregivers who participate in the main trial will be eligible to interview. An effort will be made to capture a broad range of patients, with varying degrees of age (including those >85 years), frailty (including those with Frailty Index >0.4) and medical comorbidities.<sup>28 29</sup> Of note, the GOAL trial protocol excludes patients with significant cognitive impairment who cannot consent for themselves. However, trial patients with mild cognitive impairment will be included. Given that we will rely on approached patients to consent to the interviews, convenience sampling will also be necessary, in addition to the purposive sampling described above. We will attempt to include a mix of geriatricians, nephrologists, research coordinators, trial investigators and administrative staff. If available, we will also interview multidisciplinary health professionals. We will aim for at least four patient and one caregiver interview per intervention site, two patient or caregiver interview from each control site and a total of 20 health professional interviews, continuing until thematic saturation is achieved.

2. Recruitment: Recruitment for the patient and caregiver interviews will commence when each site has completed all follow-up for all patients (ie, when the last patient at that site has completed their 12-month follow-up). Recruitment for health professionals will occur when all sites have completed all follow-up. This decision was made to prevent contamination and bias from the process evaluation affecting the main trial outcomes.
3. Consent for interviews: Written consent will be obtained for all participants interviewed. Consent for the interviews is not necessary for patient participation in the main trial.
4. Interview processes: Interviews will be conducted via audio-visual communication or telephone and will be audio-recorded using a digital recording device. Field notes may also be taken. Interview questions will be open-ended and phrased to encourage patients to discuss their own experiences and opinions. Medical and research jargon will be avoided. No repeat interviews will be carried out. Each interview will take approximately 30–60 min. Transcripts will not be returned to participants. No non-participants will be present for the interview. Interviews of caregivers can be conducted individually or dyadically.
5. Interview guides: Copies of the interview guides for research coordinators, geriatricians, nephrologists, patients and caregivers are available as online supplemental appendices C-G.

### Analysis of data

All implementation data (issues register, recruitment emails, trial site meetings) will be logged into spreadsheets. Descriptive statistics will be used to summarise issues noted in the process data (issues register as well as

recruitment discussions) and descriptive data in the CGA letters. Quantitative data about the interview participants will also be described descriptively.

The interviews will be recorded and transcribed verbatim. Pseudonyms will be used in place of patient names and as such the stored information will be in a deidentified format. All identifiable data will be stored on password-protected files. The signed consent forms for patients and caregivers will be stored by the central coordinating centre while those for the health professionals will be stored by a member of the process evaluation team.

Qualitative data, from CGA letters, process data and semistructured interviews will be analysed using a reflexive thematic analysis, underpinned by an interpretivist epistemological position, using both deductive and inductive approaches.<sup>27 30</sup> The deductive component will be informed by the programme theory and logic model developed in the first stage of the process evaluation. STF and one other team member will complete data coding. A copy of the coding tree will be provided with the published results. These will then be synthesised to further develop the programme theory that takes account of potential causal mechanisms. Participants will be invited to provide feedback on the findings. All qualitative data will be analysed with NVivo software and presented in a narrative format with excerpts of interviews included to illustrate key points.<sup>31</sup>

### Reporting guidelines

The Standards for Quality Improvement Reporting Excellence guidelines will be considered when reporting the results of the process evaluation.<sup>32</sup> The qualitative components of this work, in particular the interviews, will be reported according to the Consolidated criteria for Reporting Qualitative research guidelines.<sup>33</sup>

### Patient and public involvement

Patient and public involvement is facilitated through the GOAL Trial Consumer Advisory Board.

### ETHICS AND DISSEMINATION

Findings from this process evaluation will be published in academic journals. There will be a clear linkage to the main trial paper. Results will also be presented at scientific conferences. Feedback to consumers will be facilitated through the central coordinating centre, in consultation with the GOAL trial consumer advisory board.

Ethics approval for process evaluation, along with the main trial, was granted by the Metro South Hospital and Health Service—Metro South Human Research Ethics Committee (HREC/2020/QMS/62883). The study has received local governance approvals at each of the participating sites. Protocol amendments are submitted to and approved by the ethics committee prior to implementation.

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(Centre for Health Services Research, The University of Queensland), Angus G Ritchie (Concord Repatriation General Hospital and Faculty of Medicine and Health, University of Sydney), Matthew A Roberts (Eastern Health Clinical School, Monash University), Mona Saade (Austin Health), Shailly Saxena (Gold Coast University Hospital), Nicole Scholes-Robertson (College of Medicine and Public Health, Flinders University and Centre for Kidney Research, The Children's Hospital at Westmead), Shaundee Sen (Concord Repatriation General Hospital and Faculty of Medicine and Health, University of Sydney) Ken-Soon Tan (Logan Hospital, University of Queensland and Griffith University, Louise Waite (Concord Hospital and University of Sydney), Brioney Weaver (Logan Hospital), Vidu Wijeratne (Renal Research Gosford and Gosford Hospital), Daniel Wong (Gosford Hospital and University of Newcastle), Germaine Wong (Sydney School of Public Health, The University of Sydney and The Children's Hospital at Westmead and Westmead Hospital), Paul Andrew Yates (Austin Health and University of Melbourne), Belinda Yip (Liverpool Renal Clinical Research Centre, Liverpool Hospital). The authors acknowledge the following committees that have contributed to the trial's development and operation: The GOAL Trial Steering Committee, The GOAL Trial Management Committee, The GOAL Trial Consumer Advisory Board, The GOAL Trial Chief and Associate Investigators for the NHMRC Grant, The GOAL Trial Data and Safety Monitoring Board, AKTN Executive Operations Secretariat, AKTN Leadership Team, AKTN Project Management Team, and AKTN Scientific Committee. The support of the following study sites has been integral to this trial, and they are acknowledged with thanks: Austin Health, Blacktown Hospital, Cairns Hospital, Concord Repatriation General Hospital, Gold Coast University Hospital, Liverpool Hospital, Logan Hospital, Princess Alexandra Hospital, Renal Research Gosford, Royal Adelaide Hospital, Royal Perth Hospital, Sir Charles Gairdner Hospital, Toowoomba Hospital, Townsville Hospital and Western Health. Study data were collected and managed using REDCap electronic data capture tools hosted at The University of Queensland. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages and (4) procedures for data integration and interoperability with external sources.

**Contributors** STF developed this process evaluation protocol and was involved in planning and design of the work. RH is the lead investigator of the GOAL trial and formed the original idea and design for the trial. She was involved in planning and design of the process evaluation design. MM, AV and EK were involved in trial coordination, including planning of the work. EMA was involved in planning of data management. AV is an investigator on the GOAL trial and contributed to design and planning of this work. DJ is an investigator on the GOAL trial and contributed to design and planning of this work. MJ is an investigator on the GOAL trial. She was involved in planning and design of the process evaluation work. All authors contributed to creation of this manuscript, including reviewing and approval of the final manuscript. All authors agreed to be accountable for all aspects of the work herein. RH is the guarantor.

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**Competing interests** DJ has received consultancy fees, research grants, speaker's honoraria and travel sponsorships from Baxter Healthcare and Fresenius Medical Care, consultancy fees from Astra Zeneca, Bayer and AWAK, speaker's honoraria from ONO and Boehringer Ingelheim & Lilly, and travel sponsorships from Ono and Amgen.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not applicable.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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# GOAL Trial Recruitment Survey - PI

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## Start of Block: Default Question Block

Q1 The GOAL-CKD Trial is a cluster randomised controlled trial investigating whether comprehensive geriatric assessment can allow frail older people with chronic kidney disease to better achieve their treatment goals.

This survey is about your experiences of patient recruitment, and is part of the process evaluation of the GOAL-CKD Trial.

The GOAL-CKD Trial, including the process evaluation component, has received ethics approval through Metro South Hospital and Health Service - Metro South Human Research Ethics Committee (HREC/2020/QMS/62883).

Participation in this survey is voluntary. You will not be penalised if you don't complete this survey, and your involvement in this survey does not change or affect your involvement in the GOAL-CKD Trial more broadly.

It would be helpful for you to include your name and site ID when completing this survey. However, this is not necessary and it is ok if you prefer not to include these.

We anticipate this survey will take 5-10 minutes to complete.

If you have any questions about this survey please contact Dr Sarah Fox at [sarah.fox@uq.edu.au](mailto:sarah.fox@uq.edu.au) or the GOAL Trial coordinators at [goal@uq.edu.au](mailto:goal@uq.edu.au)

Thank you for your contribution to this survey and for your involvement in the GOAL-CKD Trial more broadly.



Q2 Was your Site involved in the GOAL-CKD trial?

- ☐ Yes (1)
- ☐ No (2)
- ☐ Unsure (99)

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Page Break



Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes

Q3 What is your Site ID/Site Name?

Please note that this information is helpful but not necessary. Even if you do not want to provide your Site ID, we would be very grateful if you completed the other questions in the survey.

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes



Q4 Was your Site an *Intervention* or *Control* Site?

- ☐ Control (1)
- ☐ Intervention (2)
- ☐ Unsure (99)

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes



Q5 What was your role in the GOAL-CKD Trial?

- ☐ Principal Investigator (PI) - Geriatrician (1)
- ☐ Principal Investigator (PI) - Nephrologist (2)
- ☐ Other (please specify) (99)

Page Break

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes



Q6 Did your Site (hospital or health service) already have an outpatient geriatrician clinic *prior* to GOAL?

- ☐ Yes (1)
- ☐ No (2)
- ☐ Unsure (99)

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes



Q7 Which clinicians were primarily looking after frail older *outpatients* with Chronic Kidney Disease prior to the GOAL-CKD trial?

- ☐ Geriatricians (1)
- ☐ Nephrologists (2)
- ☐ Both geriatricians and nephrologists (3)
- ☐ Other (Please specify) (4)
- 
- ☐ Unsure (99)

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes



Q8 In your opinion, to what extent are the patients your site *recruited for the GOAL-CKD Trial* representative of *all frail patients* with CKD at your hospital/health service?

- ☐ Very Representative (1)
- ☐ Somewhat Representative (2)
- ☐ Somewhat Unrepresentative (3)
- ☐ Very Unrepresentative (4)
- ☐ Unsure (99)

---

*Display This Question:*

*If Was your Site involved in the GOAL-CKD trial? = Yes*

*And In your opinion, to what extent are the patients your site recruited for the GOAL-CKD Trial repre... != Very Representative*

Q9 In what way were patients recruited for the GOAL Trial *NOT representative* of all frail older adults with CKD at your Site (hospital/health service)?

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Page Break

Display This Question:

*If Was your Site an Intervention or Control Site? = Intervention*

*And Was your Site involved in the GOAL-CKD trial? = Yes*



Q10 How many geriatricians were involved in providing Comprehensive Geriatric Assessment as part of the GOAL-CKD Study at your Site?

- ☐ 1 (1)
- ☐ 2 (2)
- ☐ 3 (3)
- ☐ 4 (4)
- ☐ >4 (5)
- ☐ Unsure (99)

Display This Question:

*If Was your Site involved in the GOAL-CKD trial? = Yes*

*And Was your Site an Intervention or Control Site? = Intervention*



Q11 How easy was it to find geriatricians to provide CGA for the trial?

- ☐ Extremely difficult (1)
- ☐ Somewhat difficult (2)
- ☐ Neither easy nor difficult (3)
- ☐ Somewhat easy (4)
- ☐ Extremely easy (5)
- ☐ Unsure (99)



Display This Question:

*If Was your Site an Intervention or Control Site? = Intervention*

*And Was your Site involved in the GOAL-CKD trial? = Yes*



Q12 How easy was it to find clinic space (room availability) for geriatricians to provide CGA as part of the GOAL Trial?

- ☐ Extremely difficult (1)
- ☐ Somewhat difficult (2)
- ☐ Neither easy nor difficult (3)
- ☐ Somewhat easy (4)
- ☐ Extremely easy (5)
- ☐ Unsure (99)

Page Break

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes



Q13 To what degree did the Covid-19 pandemic negatively impact on recruitment for the GOAL-CKD Trial?

- ☐ Not at all (1)
- ☐ A small amount (2)
- ☐ A moderate amount (3)
- ☐ A great amount (4)
- ☐ A very great amount (5)
- ☐ Unsure (99)

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes

Q14 How did the Covid-19 pandemic negatively impact recruitment for the trial?

---

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes

And Was your Site an Intervention or Control Site? = Intervention

Q15 How did you manage outpatient scheduling to ensure clinic availability for geriatricians to provide CGA as part of the GOAL Trial?

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Page Break

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes



Q16 How supportive were *nephrologists* at your site of patients being involved in the GOAL Trial?

- ☐ Very Supportive (1)
- ☐ Somewhat Supportive (2)
- ☐ Somewhat Unsupportive (3)
- ☐ Very Unsupportive (4)
- ☐ Unsure (99)

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes



Q17 How supportive were *geriatricians* at your site of patients being involved in the GOAL Trial?

- ☐ Very Supportive (1)
- ☐ Somewhat Supportive (2)
- ☐ Somewhat Unsupportive (3)
- ☐ Very Unsupportive (4)
- ☐ Unsure (99)

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes



Q18 How supportive were *hospital executive/management* at your site of patients being involved in the GOAL Trial?

- ☐ Very Supportive (1)
- ☐ Somewhat Supportive (2)
- ☐ Somewhat Unsupportive (3)
- ☐ Very Unsupportive (4)
- ☐ Unsure (99)

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Page Break



Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes

Q19 What factors *supported or assisted* patient recruitment at your Site?

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Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes

Q20 From your perspective, what were the *barriers or challenges* to patient recruitment at your Site?

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Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes

Q21 In retrospect, what could have been *done differently* (trial design, trial management, site organisation etc) to improve recruitment?

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Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes

Q22 Is there anything else you would like to say about recruitment for the GOAL Trial?

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Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes

Q23 If you are happy to leave your name, please enter it here:

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End of Block: Default Question Block

---

# GOAL Trial Recruitment Survey - Research Coordinators

---

## Start of Block: Default Question Block

Q1 The GOAL-CKD Trial is a cluster randomised controlled trial investigating whether comprehensive geriatric assessment (CGA) can allow frail older people with chronic kidney disease to better achieve their treatment goals.

This survey is about your experiences of patient recruitment, and is part of the process evaluation of the GOAL-CKD Trial.

The GOAL-CKD Trial, including the process evaluation component, has received ethics approval through Metro South Hospital and Health Service - Metro South Human Research Ethics Committee (HREC/2020/QMS/62883).

Participation in this survey is voluntary. You will not be penalised if you don't complete this survey, and your involvement in this survey does not change or affect your involvement in the GOAL-CKD Trial more broadly.

It would be helpful for you to include your name and Site ID when completing this survey. However, it is not necessary and it is ok if you prefer not to include these.

We anticipate this survey will take 5-10 minutes to complete.

If you have any questions about this survey please contact Dr Sarah Fox at [sarah.fox@uq.edu.au](mailto:sarah.fox@uq.edu.au) or the GOAL Trial coordinators at [goal@uq.edu.au](mailto:goal@uq.edu.au)

Thank you for your contribution to this survey and for your involvement in the GOAL-CKD Trial more broadly.



Q2 Was your Site involved in the GOAL-CKD trial?

- ☐ Yes (1)
- ☐ No (2)
- ☐ Unsure (99)

---

Page Break

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes

Q3 What is your Site ID/Site Name? (optional)

Please note that this information is helpful but not necessary. Even if you do not want to provide your Site ID, we would be very grateful if you completed the other questions in the survey.

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes



Q4 Was your Site an *Intervention* or *Control* Site?

- ☐ Control (1)
- ☐ Intervention (2)
- ☐ Unsure (99)

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes



Q5 What was your role in the GOAL-CKD Trial?

- ☐ Research Coordinator or Research Nurse (1)
- ☐ Other (please specify) (99)

Page Break



Display This Question:

*If Was your Site involved in the GOAL-CKD trial? = Yes*

*And Was your Site an Intervention or Control Site? = Intervention*



Q6 How many geriatricians were involved in providing Comprehensive Geriatric Assessment as part of the GOAL-CKD Study at your Site?

- ☐ 1 (1)
- ☐ 2 (2)
- ☐ 3 (3)
- ☐ 4 (4)
- ☐ >4 (5)
- ☐ Unsure (99)

Display This Question:

*If Was your Site involved in the GOAL-CKD trial? = Yes*

*And Was your Site an Intervention or Control Site? = Intervention*



Q7 How easy was it to find geriatricians to provide Comprehensive Geriatric Assessment (CGA) at your site?

- ☐ Very Easy (1)
- ☐ Somewhat Easy (2)
- ☐ Somewhat Difficult (3)
- ☐ Very Difficult (4)
- ☐ Unsure (99)

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes



Q8 From *where* were trial participants predominantly recruited?

- ☐ Dialysis outpatients (1)
  - ☐ Renal outpatient department (Non-Dialysis) (2)
  - ☐ Inpatients - Renal ward (3)
  - ☐ Inpatients - Other wards (4)
  - ☐ Emergency Department (5)
  - ☐ General Practice (GP) (6)
  - ☐ Other (Please specify) (99)
- 

Display This Question:

If Was your Site an Intervention or Control Site? = Intervention

And Was your Site involved in the GOAL-CKD trial? = Yes



Q9 Did patients require a GP referral to have a Geriatrician assessment (CGA) as part of this trial?

- ☐ Yes (1)
  - ☐ No (2)
  - ☐ Unsure (99)
-

Page Break

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Display This Question:

*If Was your Site involved in the GOAL-CKD trial? = Yes*



Q10 To what degree did the Covid-19 pandemic negatively impact on recruitment for the GOAL-CKD Trial?

- ☐ Not at all (1)
- ☐ A small amount (2)
- ☐ A moderate amount (3)
- ☐ A great amount (4)
- ☐ A very great amount (5)
- ☐ Unsure (99)

Display This Question:

*If Was your Site involved in the GOAL-CKD trial? = Yes*

*And To what degree did the Covid-19 pandemic negatively impact on recruitment for the GOAL-CKD Trial? != Not at all*

Q11 In what way did the Covid-19 pandemic negatively impact recruitment for the trial?

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Page Break

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes



Q12 How much did transport requirements (e.g. transport to trial appointments) negatively impact recruitment at your site?

- ☐ None at all (1)
- ☐ A little (2)
- ☐ A moderate amount (3)
- ☐ A lot (4)
- ☐ A great deal (5)
- ☐ Unsure (99)

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes



Q13 To what extent were time constraints for the *patient* (e.g. time for appointments) a reason for patients not wanting to participate in the trial?

- ☐ None at all (1)
- ☐ A little (2)
- ☐ A moderate amount (3)
- ☐ A lot (4)
- ☐ A great deal (5)

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes



Q14 To what extent were time constraints for the *caregiver* (e.g. time for appointments) a reason for patients not wanting to participate in the trial?

- ☐ None at all (1)
- ☐ A little (2)
- ☐ A moderate amount (3)
- ☐ A lot (4)
- ☐ A great deal (5)
- ☐ Unsure (99)

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes



Q15 To what extent were costs associated with parking a reason for patients not wanting to participate in the trial?

- ☐ None at all (1)
- ☐ A little (2)
- ☐ A moderate amount (3)
- ☐ A lot (4)
- ☐ A great deal (5)
- ☐ Unsure (99)

Page Break





Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes

Q16 What factors *supported or assisted* patient recruitment at your Site?

---

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes

Q17 From your perspective, what were the *barriers or challenges* to patient recruitment at your Site?

---

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes

Q18 In retrospect, what could have been *done differently* (trial design, trial management, site organisation etc) to improve recruitment?

---

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes

Q19 Is there anything else you would like to say about recruitment for the GOAL Trial?

---

Display This Question:

If Was your Site involved in the GOAL-CKD trial? = Yes

Q20 If you are happy to leave your *name*, please enter it here:

---

End of Block: Default Question Block



## Interview Guide for Research coordinators/Research staff/Administrative staff

### Introduction

The interview is about your experience of the GOAL study, in which patients with chronic kidney disease saw a geriatrician in an outpatient clinic.

Thank you for discussing your experiences. You have a unique perspective in helping us understand what in the study worked well and what didn't. There are no right or wrong answers; your personal views and experiences are what interest me.

The decision to be involved in this interview is entirely up to you. If at any point there are questions you do not want to answer please let me know – you do not have to answer any question if you don't want to.

With your permission I would like to record our conversation today so that I can listen carefully and later on re-listen to the recording to extract the most useful aspects. We take your confidentiality very seriously. When we transcribe the interviews we will remove any details that might identify you. We then collate the responses from your interview and the interviews with other people. Your name will never be published as one of the individuals who participated in the interview part of this research and it will not be possible to identify you from any material published from this interview.

Is it ok with you if I record our conversation today?

<Start recording>

### 1. Health professional background

Firstly, could you please briefly describe your previous experience in working with older people?

Prompts:

- Did you already have experience of working with the renal physicians and geriatricians in this hospital?
- Did you have experience in the outpatient clinic here?
- What role were you in prior to, and at the time of, the GOAL trial

### 2. Role in the GOAL Study

Do you remember the GOAL Study? Are you able to talk with me about where you fit into the GOAL Study and what your role in it was?

Prompts:

- role in recruitment
- role in data collection
- role in getting geriatricians/stakeholders on board

### 3. Perceived value of the GOAL trial

Why did you agree to participate in the GOAL trial?

Prompts:

- What were the foreseen advantages of you or your site being involved?
- Were there things that you were worried would be difficult when you were deciding whether to participate?

**4. Implementation of CGA, including barriers and enablers**

Can you describe how the CGA, the assessment where the patient was seen by the geriatrician, was incorporated into the outpatient clinic?

*Prompts:*

- How did it run logistically?
- Were there any challenges in setting it up?
- Was it difficult to get referrals from GPs/specialists?
- How it was billed
- Was it hard to find clinic space?
- Was it hard to find a geriatrician?

**5. Recruitment**

How were patients recruited and how well did this process of recruitment run?

*Prompts:*

- Do you think the patients who were included were representative of most frail older people with CKD?
- Were patients willing? Why did some people say no?
- How onerous was recruitment? Was it hard to get nephrologists on board? Was it hard to coordinate the geriatric and nephrology care?

**6. GAS**

What was your experience of doing GAS with the patient?

*Prompts:*

- What were the good and bad things about this?
- How much did the GAS you did in practice reflect what you learnt about GAS at the start of the study?
- What were the challenges and what do you think could be improved?

**7. Barriers and Enablers and Maintenance**

What were the barrier and enablers to embedding CGA into the care of older adults with CKD? Did this change over time?

*Prompts:*

- Did you change your processes over the 2 years that the trial was running? If so why?
- What were the barriers and challenges to recruitment, implementation and patient care that you face
- 

**8. CGA Acceptability and Value**

Based on your experiences with this study, do you think it would be good to have a geriatrician integrated into the care team for older frail patients with chronic kidney disease? If yes, why; if no, why not? *Prompts:*

- Positive things: benefits of in-depth assessment of goals of patients; good to share the care for frail patients
- Negative things: decision making can be done with another health care professional already; patients feel too unwell or overwhelmed at the time; kidney team is taking good care of the patients; patients already have multiple providers - adding the geriatrician makes it more complex; geriatrician comes

and goes but we must then action the prescriptions/plans, that is the hard part; geriatricians explanations come too late; patients already set their mind on a path forward etc.)

- Did you speak to others about the intervention, and would you recommend other teams to integrate a comprehensive geriatric assessment into their care pathways?

-

#### **9. Wellbeing**

Did the intervention/study impact your own work and wellbeing? If yes, in what way? If no, why not?

#### **10. Other**

Would you have any other comments to share of the overall experience of the intervention over time in your clinic and how the patients, the team or you were impacted by it?

Thank you very much for your time.



## Interview Guide for Geriatricians

### Introduction

The interview is about your experience of the GOAL study, in which patients with chronic kidney disease saw a geriatrician in an outpatient clinic.

Thank you for discussing your experiences. You have a unique perspective in helping us understand what in the study worked well and what didn't. There are no right or wrong answers; your personal views and experiences are what interest me.

The decision to be involved in this interview is entirely up to you. If at any point there are questions you do not want to answer please let me know – you do not have to answer any question if you don't want to.

With your permission I would like to record our conversation today so that I can listen carefully and later on re-listen to the recording to extract the most useful aspects. We take your confidentiality very seriously. When we transcribe the interviews we will remove any details that might identify you. We then collate the responses from your interview and the interviews with other people. Your name will never be published as one of the individuals who participated in the interview part of this research and it will not be possible to identify you from any material published from this interview.

Is it ok with you if I record our conversation today?

*<Start Recording>*

### 1. Health professional background

Firstly, could you please briefly describe your previous experience in working with frail older people with chronic kidney disease? And also your hospitals processes and programs for frail older adults with CKD, that were already up and running prior to this study starting?

*Prompts:*

- Did you already have experience of working with the renal physicians in this hospital?
- Were you already seeing a lot of patients with CKD?
- What were the relationships like between nephrology and geriatric medicine?
- Did you have geriatric clinics here in the OP prior to the study starting? Did you see many referrals from nephrologists in these clinics?
- Who was looking after older adults with CKD? Geriatricians or nephrologists?

### 2. Role in the GOAL Study

Do you remember the GOAL Study? Are you able to talk with me about where you fit into the GOAL Study and what your role in it was?

*Prompts:*

- role in leading/coordinating study
- role in seeing patients
- role in following up patients?
- Assessment of eligibility/recruitment process?

- role in booking times for geriatricians/clinic rooms
- role in making sure the CGA and the GAS happened close together
- Were you a PI? Member of TSC?

### 3. Perceived value of the GOAL trial

Why did you agree to participate in the GOAL trial? Did you think that the intervention would be beneficial?

Prompts:

- What were the foreseen advantages of you or your site being involved?
- Were there things that you were worried would be difficult when you were deciding whether to participate?
- Did you think the trial would benefit patients?
- Did you think the trial/intervention would be beneficial for your site?
- What were you worried wouldn't work/might be difficult with the study?

### 4. Implementation

Can you describe how the CGA, was incorporated into the outpatient clinic? Prompts:

- How did it run logistically?
- Were there any challenges in setting it up?
- Was it difficult to get referrals from GPs/specialists?
- How it was billed
- Was it hard to find clinic space?
- How much did the CGA you provided in this trial reflect your real-world practice?
- 

### 5. CGA Acceptability and Value

Based on your experiences with this study, do you think it would be good to have a geriatrician integrated into the care team for older frail patients with chronic kidney disease? If yes, why; if no, why not?

Prompts:

- Can you describe to me what it is about the CGA intervention, including what happened during the consultation and what the follow-up /review, that makes it beneficial or not??

-

### 6. Processes – Communication and Information Sharing

Can you describe the processes of communication and information sharing when providing CGA as part of the trial?

Prompts:

- How much did you communicate with the nephrologists?
- How did you communicate with the GP?
- How did you communicate with the MDT?
- Was the communication ongoing or just a single moment?
- How adequate was the medical record/information transfer system?

**7. Process – Goal setting and Care planning**

Patients in this trial set goals (GAS). Did you discuss patients goals, set during the trial with them? If so is this different to your usual care? Did you discuss other goals?

Prompts:

- Did you have access to the frailty index and did this change the assessment?
- Did you have access to the GAS and did this change the assessment?

**8. Processes – follow-up and review**

What follow-up and review did you have for the patients you saw in the trial?

Prompts:

- Did you see patients again and follow-up their progress?
- To what degree did you feel you took ownership of their care? And to what degree did most ownership stay with the nephrologist or GP?

**9. Barriers and Enablers**

What things improved or hindered the delivery of CGA for patients with CKD?

- What aspects of the hospital system/people with whom you work could have been improved?
- Were there supports/people in place that made it easier to care for patients in this setting?
- Were there supports/people in place that made it harder to care for people?
- What could be changed about the system in which you work to make CGA more accessible and more effective?
- Were there any additional costs to your unit or to the patients or carers by integrating the intervention in routine care?

**10. Wellbeing**

Did the intervention/study impact your own work and wellbeing? If yes, in what way? If no, why not?

**11. Other**

Would you have any other comments to share of the overall experience of the intervention over time in your clinic and how the patients, the team or you were impacted by it?

Thank you very much for your time.

## Interview Guide for Nephrologists

### Introduction

The interview is about your experience of the GOAL study, in which patients with chronic kidney disease saw a geriatrician in an outpatient clinic.

Thank you for discussing your experiences. You have a unique perspective in helping us understand what in the study worked well and what didn't. There are no right or wrong answers; your personal views and experiences are what interest me.

The decision to be involved in this interview is entirely up to you. If at any point there are questions you do not want to answer please let me know – you do not have to answer any question if you don't want to.

With your permission I would like to record our conversation today so that I can listen carefully and later on re-listen to the recording to extract the most useful aspects. We take your confidentiality very seriously. When we transcribe the interviews we will remove any details that might identify you. We then collate the responses from your interview and the interviews with other people. Your name will never be published as one of the individuals who participated in the interview part of this research and it will not be possible to identify you from any material published from this interview.

Is it ok with you if I record our conversation today?

*<Start recording>*

### 1. Health professional background

Firstly, could you please briefly describe your previous experience in working with frail older people with chronic kidney disease? And also your hospitals processes and programs for frail older adults with CKD, that were already up and running prior to this study starting?

*Prompts:*

- What role were you in prior to, and at the time of, the GOAL trial?
- Were you already seeing a lot of patients with CKD who were older and frail?
- What were the relationships like between nephrology and geriatric medicine?
- Who was looking after older adults with CKD? Geriatricians or nephrologists?
- Has it been difficult to have patients seen by a geriatrician in the past?
- How established and effective were the care pathways for frail older adults with CKD, prior to this study commencing?

### 2. Role in the GOAL Study

Do you remember the GOAL Study? Are you able to talk with me about where you fit into the GOAL Study and what your role in it was?

*Prompts:*

- Role in recruitment
- Role in data collection
- Role in getting geriatricians/stakeholders on board
- Were you a PI? Member of TSC?
- 

### 3. Perceived value of the GOAL trial

Why did you agree to participate in the GOAL trial? Did you think that the intervention would be beneficial?

*Prompts:*

- What were the foreseen advantages of you or your site being involved?
- Were there things that you were worried would be difficult when you were deciding whether to participate?
- Did you think the trial would benefit patients?
- Did you think the trial/intervention would be beneficial for your site?
- What were you worried wouldn't work/might be difficult with the study?

#### **4. Implementation and Processes of CGA**

Can you describe how the CGA, the assessment where the patient was seen by the geriatrician, was incorporated into the outpatient clinic?

*Prompts:*

- Were there any challenges in setting it up?
- How much did you communicate with the geriatricians providing the CGA? Did you receive a letter from the geriatrician? Did you discuss the patient verbally either in person or over the phone?
- How adequate was the information sharing between you and the geriatrician?
- Did you continue to see patients who had been seen by geriatricians? Why or why not?
- Your interactions with patients and carers who received this intervention differed from the usual care pathway.
- Did you change your management based on the geriatricians' recommendations?

#### **5. Recruitment**

How were patients recruited and how well did this process of recruitment run?

*Prompts:*

- Do you think the patients who were included were representative of most frail older people with CKD?
- Were patients willing? Why did some people say no?
- How did you decide who to screen/include in the trial? Did other trials running simultaneously mean that the patients included in the GOAL trial were not representative?
- 

#### **6. GAS**

Patients in this trial set goals (GAS). Did you discuss patients' goals, set during the trial with them? If so, is this different to your usual care?

#### **7. CGA Acceptability and Value**

Based on your experiences with this study, do you think it would be good to have a geriatrician integrated into the care team for older frail patients with chronic kidney disease? If yes, why; if no, why not? *Prompts:*

- Positive things: benefits of in-depth assessment of goals of patients; good to share the care for frail patients.
- Negative things: decision making can be done with another health care professional already; patients feel too unwell or overwhelmed at the time;

kidney team is taking good care of the patients; patients already have multiple providers - adding the geriatrician makes it more complex; geriatrician comes and goes but we must then action the prescriptions/plans, that is the hard part; geriatricians explanations come too late; patients already set their mind on a path forward etc.)

- Did you speak to others about the intervention, and would you recommend other teams to integrate a comprehensive geriatric assessment into their care pathways?

#### **8. Barriers and Challenges**

What were the challenges associated with patients receiving CGA as part of this trial?

- What are the barriers in referring patients to geriatricians
- Did the trial and geriatrician assessment increase or decrease your workload?

#### **9. Wellbeing**

Did the intervention/study impact your own work and wellbeing? If yes, in what way? If no, why not?

#### **10. Other**

Would you have any other comments to share of the overall experience of the intervention over time in your clinic and how the patients, the team or you were impacted by it?

Thank you very much for your time.



## Interview Guide for Patients

### Introduction

The interview is about your experience of being a participant in the GOAL study. In this study you saw a geriatrician in the outpatient clinic.

Thank you for discussing your experiences. You have a unique perspective in helping us understand what in the study worked well and what didn't. There are no right or wrong answers; your personal views and experiences are what interest me.

The decision to be involved in this study is entirely up to you. If at any point there are questions you do not want to answer please let me know – you do not have to answer any question if you don't want to.

With your permission I would like to record our conversation today so that I can listen carefully and later on re-listen to the recording to extract the most useful aspects. We take your confidentiality very seriously. When we transcribe the interviews we will remove any details that might identify you. We then collate the responses from your interview and the interviews with other people. Your name will never be published as one of the individuals who participated in the interview part of this research and it will not be possible to identify you from any material published from this interview.

Is it ok with you if I record our conversation today?

<Start recording>

### 1. Recruitment

Are you able to describe how you came to be involved in the GOAL study and why you agreed to be involved?

*Prompts*

- Why did you agree to participate in this study?
- What were you hoping might be the positive outcomes?
- Were there any factors that made you hesitant or unsure when deciding whether to participate?
- How did the nephrologist or nurse frame the benefits/harms when talking about the study?

### 2. Experience of CGA

As part of the trial, you had consultation with a geriatrician. Can you remember that assessment and consultation by the geriatrician and can you tell me how that went?

*Prompts*

- What did you understand would happen in the assessment?
- Is what actually happened in the geriatrician appointment different to what you expected?
- Did you discuss the goals you had previously identified?
- What was the geriatrician most interested in?
- What were the outcomes from that assessment?
- Which parts of the assessment held the most value for you?

### 3. Goal Attainment Scaling

Do you remember doing the goal-setting with the research coordinator prior to seeing the geriatricians? How helpful was this and how did it frame what you discussed when you did see the geriatrician?

*Prompts:*

- Do you think there was value in doing this GAS? What was it?
- Were the goals meaningful and relevant to you?
- Did you discuss the goals with the geriatrician?
- Did you have a plan for how to achieve your goals, and did the consultation with the geriatrician assist with this?
- Did you discuss your health goals with the geriatrician? What was your experience of this? How did this impact on your treatment and wellbeing choices at the time, and over time?

#### **4. Role of MDT**

Did the appointment with the geriatrician lead to other assessments or appointments? E.g. , occupational therapist, social worker, counsellor or other doctor?

*Prompts:*

- Were these consultations useful?
- Were they important to reach your goal?
- Did you get a sense of the MDT being 'on the same page'?
- Did you sense that the MDT were communicating with each other?

#### **5. Acceptability and value of CGA**

Would you like to have similar consultation with this geriatrician again? If yes, why; if no, why not?

*Prompts:*

- Did you feel that the geriatrician consultation added value? Was the consultation helpful?
- What were the positive aspects of the consultation?
- Was there anything that did not go so well for you in that conversation or that you would have liked to be done differently?
- What were the negative aspects of the consultation? E.g. care and decision making already happening with another team, too sick, too overwhelmed with appointments, seeing geriatrician too late, lack of continuity etc
- Were there any unexpected positive or negative outcomes of the assessment?
- Overall would you recommend this consultation to others?
- Did the consultant impact your quality of life?

#### **6. Barriers and Challenges**

Was there anything that made it difficult for you to participate in the geriatrician consultation?

- Was transport to the appointment difficult?
- Did the appointments take up too much time?
- Were there other reasons for why the conversation was not so helpful – maybe felt too unwell or overwhelmed at the time?
- Were there any additional costs to you because of the geriatrician assessment?

**7. Processes**

What was it about the consultation that made it a positive or negative experience?

*Prompts:*

- Did the geriatrician involve you in the plan and decision-making?
- Did the geriatrician understand your concerns?
- Was communication adequate?
- Was there good rapport with the geriatrician?
- 

**8. Wellbeing**

Did the intervention/study impact your own work and wellbeing? If yes, in what way? If no, why not?

**9. Other**

Would you like to make any other comments about your experience of being involved in the trial, or having the geriatrician assessment?

Any other comments before we close?

Thank you very much for your time. We really appreciate the effort you have gone to share your experiences and improve our knowledge about this trial.

## 1 Interview Guide for Caregivers

### 2 Introduction

3 The interview is about your experience of being a caregiver participant in the GOAL study. In this  
4 study your (friend/partner/etc) saw a geriatrician in the outpatient clinic.

5 Thank you for discussing your experiences. You have a unique perspective in helping us understand  
6 what in the study worked well and what didn't. There are no right or wrong answers; your personal  
7 views and experiences are what interest me.

8 The decision to be involved in this study is entirely up to you. If at any point there are questions you  
9 do not want to answer please let me know – you do not have to answer any question if you don't  
10 want to.

11 With your permission I would like to record our conversation today so that I can listen carefully and  
12 later on re-listen to the recording to extract the most useful aspects. We take your confidentiality  
13 very seriously. When we transcribe the interviews we will remove any details that might identify  
14 you. We then collate the responses from your interview and the interviews with other people. Your  
15 name will never be published as one of the individuals who participated in the interview part of this  
16 research and it will not be possible to identify you from any material published from this interview.

17 Is it ok with you if I record our conversation today?

18 <Start recording>

### 19 1. Caregiver relationship

20 What is your relationship to the trial participant?

21

### 22 2. Recruitment

23 Are you able to describe how you came to be involved in the GOAL study and what your  
24 thoughts were about your (friend/partner/parent etc) being involved?

25 Prompts

- 26 • Were you involved in their decision to be part of the study?
- 27 • Why did they agree to participate in this study?
- 28 • What were you hoping might be the positive outcomes?
- 29 • Were there any factors that made you or them hesitant or unsure when deciding  
30 whether they should participate?
- 31 • How did the nephrologist or nurse frame the benefits/harms when talking about the  
32 study?

33

### 34 3. Experience of CGA

35 As part of the trial, you had consultation with a geriatrician. Can you remember that  
36 assessment and consultation by the geriatrician and can you tell me how that went?

37 Prompts

- 38 • Were you present for the consultation?
- 39 • Did you feel engaged and included?
- 40 • If you weren't present why was that?
- 41 • What did you understand would happen in the assessment?
- 42 • Is what actually happened in the geriatrician appointment different to what you  
43 expected?

- 1 • Did you discuss the goals you had previously identified?
- 2 • What was the geriatrician most interested in?
- 3 • What were the outcomes from that assessment?
- 4 • Which parts of the assessment held the most value for you?
- 5

#### 6 **4. Goal Attainment Scaling**

7 Do you remember them doing the goal-setting with the research coordinator prior to seeing  
8 the geriatricians? How helpful was this and how did it frame the discussion when you did see  
9 the geriatrician?

10 *Prompts:*

- 11 • Do you think there was value in doing this GAS? What was it?
- 12 • Did the goals seem relevant, meaningful and achievable?
- 13 • If you weren't present for the discussion, did you (friend/partner etc) discuss the
- 14 goals with you?
- 15

#### 16 **5. Role of MDT**

17 Did the appointment with the geriatrician lead to other assessments or appointments? E.g. ,  
18 occupational therapist, social worker, counsellor or other doctor?

19 *Prompts:*

- 20 • Were these consultations useful?
- 21 • Did you get a sense of the MDT being 'on the same page'
- 22 • Did you sense that the MDT were communicating with each other?
- 23

#### 24 **6. Acceptability and Value of CGA**

25 Would you like to have similar consultation with this geriatrician again? Based on your  
26 experiences with this study, do you think it would be good to have a geriatrician integrated  
27 into the care team for older frail patients with chronic kidney disease? If yes, why; if no, why  
28 not?

29 *Prompts:*

- 30 • Did you feel that the geriatrician consultation added value? Was the consultation
- 31 helpful?
- 32 • What were the positive aspects of the consultation?
- 33 • Was there anything that did not go so well for you in that conversation or that you
- 34 would have liked to be done differently?
- 35 • What were the negative aspects of the consultation? E.g. care and decision making
- 36 already happening with another team, too sick, too overwhelmed with
- 37 appointments, seeing geriatrician too late, lack of continuity etc
- 38 • Were there other reasons for why the conversation was not so helpful – maybe felt
- 39 too unwell or overwhelmed at the time?
- 40 • Were there any unexpected positive or negative outcomes of the assessment?
- 41 • Overall would you recommend this consultation to others?
- 42 • Did the consultation impact your quality of life?
- 43

#### 44 **7. Barriers**

45 Was there anything that made it difficult for you to participate in the geriatrician  
46 consultation?

- 47 • Was transport to the appointment difficult?

- 1                   • Did the appointments take up too much time?
- 2                   • Were there any additional costs to you because of the geriatrician assessment?
- 3
- 4       **8. Processes**
- 5       What was it about the consultation that made it a positive or negative experience?
- 6       *Prompts:*
- 7                   • Did the geriatrician involve you in the plan and decision-making?
- 8                   • Did the geriatrician understand your concerns?
- 9                   • Was communication adequate?
- 10                  • Was there good rapport with the geriatrician?
- 11                  •
- 12       **9. Wellbeing**
- 13       Did the intervention/study impact your own work and wellbeing? If yes, in what way? If no,
- 14       why not?
- 15
- 16       **10. Other**
- 17       Would you like to make any other comments about your experience of being involved in the
- 18       trial, or having the geriatrician assessment?
- 19   Any other comments before we close?
- 20   Thank you very much for your time. We really appreciate the effort you have gone to share your
- 21   experiences and improve our knowledge about this trial.
- 22