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Self-reported MeasUrement of Physical and PsychosOcial Symptoms Response Tool (SUPPORT-dialysis): systematic symptom assessment and management in patients on in-centre haemodialysis – a parallel arm, non-randomised feasibility pilot study protocol

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ABSTRACT

Introduction Patients with kidney failure experience symptoms that are often under-recognised and undermanaged. These symptoms negatively impact health-related quality of life and are associated with adverse clinical outcomes. Regular symptom assessment, using electronic patient reported outcomes measure (ePROMs) linked to systematic symptom management, could improve such outcomes. Clinical implementation of ePROMs have been successful in routine oncology care, but not used for patients on dialysis. In this study, we describe a pilot study of ePROM-based systematic symptom monitoring and management intervention in patients treated with in-centre haemodialysis.

Methods and analysis This is a parallel-arm, controlled pilot of adult patients receiving in-centre maintenance haemodialysis. Participants in the intervention arm will complete ePROMs once a month for 6 months. ePROMs will be scored real time and the results will be shared with participants and with the clinical team. Moderate-severe symptoms will be flagged using established cut-off scores. Referral options for those symptoms will be shared with the clinical team, and additional symptom management resources will also be provided for both participants and clinicians. Participants in the control arm will be recruited at a different dialysis unit, to prevent contamination. They will receive usual care, except that they will complete ePROMs without the presentation of results to participants of the clinical team. The primary objectives of the pilot are to assess (1) the feasibility of a larger, randomised clinical effectiveness trial and (2) the acceptability of the intervention. Interviews conducted with participants and staff will be assessed using a content analysis approach.

Ethics and dissemination Ethical approval for this study was obtained from the University Health Network (REB#21-5199) and the William Osler Health System (#23-0005). All study procedures will be conducted in accordance with the standards of University Health Network research ethics board and with the 1964 Helsinki declaration and its later amendments. Results of this study will be shared with participants, patients on dialysis and other stakeholders using lay language summaries, oral presentations to patients and nephrology professionals. We will also be publishing the results in a peer-reviewed journal and at scientific meetings.

Protocol version 4 (16 November 2022).

Trial registration number NCT05515991.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This pilot was designed in consultation with professional and patient stakeholders.
⇒ Clear parameters are set for deciding if an effectiveness trial is feasible.
⇒ A non-randomised study design was used.
⇒ No formal sample size calculation was performed.

INTRODUCTION

In Canada, 20 000–25 000 patients receive dialysis for kidney failure.[1] Up to 50%–70% of these patients experience physical (eg, pain, itchiness, fatigue) and psychological (anxiety, depression) symptoms.[2–13] These symptoms are associated with poor health-related quality of life (HRQOL),[14 15] poor treatment adherence,[16 17] increased morbidity,[16] hospitalisation[18–20] and mortality.[17 21 22] In part due to the lack of systematic symptom assessment in dialysis care, these symptoms frequently remain unrecognised and unmanaged.

Valid and reliable patient-reported outcome measures (PROMs) can aid systematic symptom screening and monitoring

to inform symptom management. Such use of PROMs improved patient–provider communication, enabled complete assessment of patient-centred concerns and enhance patient engagement in cancer care.[23–25] It may also improve adherence to treatment, HRQOL[26 27] and survival.[28] Recent technological advancements enable electronic administration of PROMs (ePROMs), offering immediate results for clinicians and patients at the point of care. This may facilitate integrated and collaborative symptom management and self-management support. In addition, the use of ePROMs allows for computer adaptive testing (CAT), which personalises questions and reduces questionnaire burden for patients while maintaining superb measurement precision.[29–31]

The US National Institute of Health-funded Patient Reported Outcome Measures Information System (PROMIS) has developed generic item banks to assess emotional, physical and social domains of health that are relevant for people with diverse chronic medical conditions. PROMIS item banks can be administered as fixed length short forms or as CATs.[32–34] The brevity of PROMIS-CAT assessment (>80% of participants requires only 4–6 items to achieve >0.90 reliability) makes these tools appealing for routine research and clinical use.[33 34]

Limited evidence on the routine use of ePROMs has demonstrated their potential to improve outcomes and enrich the patient experience.[35–41] The Distress Assessment and Response Tool (DART),[42] implemented for routine distress screening and management at the outpatient clinics of the Princess Margaret Hospital Cancer Center used an ePROM-based approach with >70% completion rate for >10 years before the COVID-19 pandemic.[43] ePROM scores guided a stepped, guideline informed, collaborative care distress management response system. In this pilot, we will use a similar approach for systematic symptom assessment and management for patients treated with maintenance in-centre haemodialysis. Specifically, participants will complete PROMIS-CAT to assess their symptoms. The symptom scores and potential management recommendations will be shared with participants and their clinical team. A non-malignant supportive/palliative care clinic will be the primary option for referral for patients with moderate–severe symptom burden. If deemed appropriate, participants may be referred to sleep, pain or medical psychiatry clinics, and social workers.

This paper describes the protocol of a parallel arm, non-randomised pilot trial of an ePROM informed systematic symptom monitoring and management approach in patients on haemodialysis. This pilot will test the acceptability of the Self-reported MeasUrement of Physical and PsychosOcial Symptoms Response Tool (SUPPORT-dialysis) intervention among patients and healthcare staff and the feasibility of a subsequent effectiveness trial.

Objectives

The objectives of this pilot are as follows:

1. To assess the feasibility of a phase III randomised-controlled trial (RCT) assessing the effectiveness of the ePROM informed systematic symptom management intervention among patients with kidney failure in routine haemodialysis care.
2. To assess the acceptability of SUPPORT-Dialysis intervention among participants and the clinical team.

Feasibility will be determined if 4 out of 4 following outcome targets are met:

1. Recruitment target will be met.
2. Decline rate: < 50%.
3. Completion rate: > 80% of participants at least 50% of the time.
4. Drop-out rate: < 30%.

These feasibility outcome thresholds are derived from general recommendations and guidelines for feasibility and implementation studies.[44–47] Similar thresholds have been used while assessing implementation of PROMIS-CAT.[37 38]

Acceptability will be met based on the following:

1. > 80% of patients will find the toolkit acceptable.
2. < 20% of staff find the process intrusive to workflow.

These acceptability outcome thresholds are derived from general recommendations and guidelines for feasibility and pilot studies.[44 47–49] Similar acceptability thresholds have been used in previous studies.[34 38]

METHODS AND ANALYSIS

Study design

This will be a multicentre parallel-arm controlled pilot study, with a 3-month enrolment period and a follow-up period of 6 months. Sixty (30 in each arm) stable adult prevalent patients on maintenance in-centre haemodialysis will be recruited. Potentially eligible patients will be identified by a member of the clinical team. Interested participants will be screened by qualified research assistants and written informed consent will be obtained subsequently.

Study setting

The study will take place at two haemodialysis centres in the Greater Toronto Area, Ontario, Canada. Out of four dialysis sites that initially expressed interest in participating in the study, Toronto General Hospital and William Osler Health System were selected based on their readiness (assessed by the DART readiness survey) and willingness to participate. Patients treated at the haemodialysis unit at Toronto General Hospital will be enrolled in the intervention arm and patients at the dialysis units at William Osler Health System will be enrolled in the control arm. Assigning the intervention to Toronto General Hospital was a decision made to facilitate the timely initiation of the study. As Princess Margaret Hospital and Toronto General Hospital are both part of the University Health Network, the intervention site already had the ePROM platform integrated into the electronic patient record.

Table 1 Inclusion and exclusion criteria

Inclusion	Exclusion
i. Age≥18 years ii. Patients undergoing maintenance haemodialysis for more than 3 months	i. Presence of severe acute illness or condition that hampers questionnaire completion ii. Unable to understand English at a grade 5 level iii. Dementia indicated in the medical record or by managing healthcare team iv. Life expectancy of <6 months as determined the managing nephrology team v. Expected transplant within 6 months as indicated by the managing nephrology team vi. Planned transfer to peritoneal dialysis within 6 months as indicated by the managing nephrology team vii. Unwilling or unable to provide informed consent

Furthermore, there was awareness and engagement of ePROMs at multiple levels of the different stakeholders.

Public and patient involvement

A Patient and Caregiver Advisory Panel was convened that included patients with lived experiences of dialysis and transplantation and caregivers of such patients. The panel provided insight about symptom experience, information and management needs. The panel was also closely involved in testing the usability of the output report and an online resource for symptom self-management support (https://symptomcare.org/).

Participant selection

We will recruit individuals who have stage 5 chronic kidney disease (CKD) and have been receiving haemodialysis for more than 3 months. Table 1 presents inclusion and exclusion criteria.

Sample size consideration

No formal sample size calculation was performed. Sample size was informed by general recommendations in the literature and feasibility considerations. The proposed feasibility outcomes will demonstrate that we can recruit an appropriate number of patients for a larger, randomised control trial. The final sample size for this pilot is in line with general recommendations in the literature and feasibility recommendations (pilot sample size 30–60 participants per arm) to obtain sufficiently precise effect size estimates.[50 51] Currently about 450 maintenance haemodialysis patients are treated in the 2 dialysis units. We estimate that about 250 of these patients will fulfil our inclusion criteria, providing a large enough sampling frame for the pilot.

We will use the pilot outcomes of this pilot to inform the sample size considerations for the subsequent large trial. The anticipated primary outcomes assessed in the larger trial include the PROMIS mental and physical health summary scores. Secondary outcomes include the EuroQOL 5-Domain 5-Level (EQ-5D-5L) health utility score, along with the Mental and Physical Component Scores from the SF-12 and healthcare utilisation. We will use the descriptive statistics of the PROMIS summary scores obtained in our pilot (mean, SD) to estimate the required sample size to have at least 80% power to detect a 4-point change in the Mental Health Summary score (two-sided α=0.05).

Intervention

Our intervention includes

1. *Systematic symptom screening and monitoring* using the PROMIS-29 item banks (anxiety, depression, fatigue, sleep disturbance, pain interference, physical functioning, 'ability to participate in social roles and activities'—in short: social functioning) administered as CATs. Item 7 of the PROMIS global health scale v1.1 assessing pain intensity will be administered as well.
2. *Collaborative care symptom management pathways.* Participants and their clinical team will receive printed and electronic copy of their symptom output report immediately after completing the PROMs. The output report will include a link to a self-management website, developed by our team (https://symptomcare.org). We also offer free access to the Kidney Beam website (https://beamfeelgood.com/kidney-disease), whose mission is to help people living with kidney disease to feel good through movement, education and well-being support, for patients with impaired physical function. The clinical team of participants flagged for moderate–severe symptoms will receive additional suggestions for management options to the University Health Network (UHN) supportive/palliative care clinic, or to sleep, pain or medical psychiatry clinics, or social workers, as appropriate. Referral for any symptom management interventions, however, will be at the discretion of the main responsible nephrologist or nurse practitioner.

Study procedure

Participants in the intervention arm will be asked to complete PROMIS 29 item banks for anxiety v1.0, cognitive function v1.0, depression v1.0, dyspnoea severity v1.0, fatigue v1.0, pain interference v1.1, sleep disturbance v1.0, physical function v2.0 and ability to participate in social roles v2.0. All PROMIS measures will be administered as

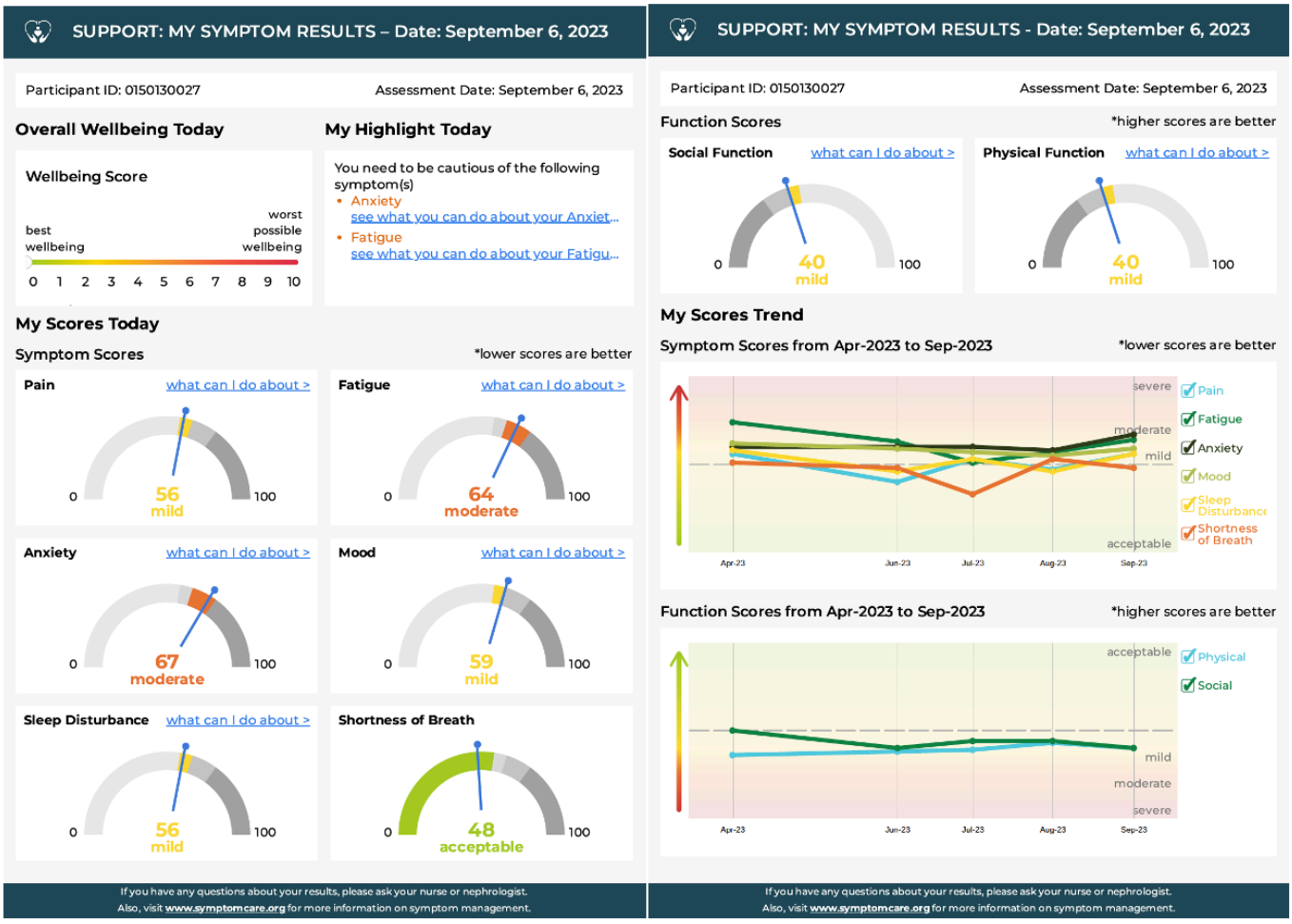

Figure 1 Example of output report generated after the completion of patient-reported outcome measures.

CATs. Participants will complete PROMIS-CATs on tablet computers[52 53] during the first 2 hours of routine dialysis visits every 4 weeks for 6 months. These will take an estimated 5–10 min to complete. The PROMIS-CATs will be scored immediately, and scores will be summarised in an 'output report' (figure 1). Symptom scores potentially indicats moderate–severe symptoms (based on predefined cut-off scores).[54–56] The output report will be shared with participants (print and electronic) and the clinical team (electronic only). Eventually, the symptom scores will be projected to patients' electronic medical records for easy access for the clinical team and for patients through the EPIC MyChart patient portal. At the time of study design, the intervention site already had the ePROM platform integrated into the electronic patient record system used at the time. However, in June 2022, EPIC replaced the previous electronic patient record. Consequently, a new ePROM platform was developed to administer the PROMIS CATs, and this will require additional integration work before ePROM results can be projected into EPIC. This work is currently nearing completion.

After completing the PROMIS CATs, participants will immediately receive a print and electronic output report. The output report will include a link to https://symptomcare.org/ where we present resources which provide support for symptom self-management, management recommendations and information about maintaining well-being for both patients and healthcare professionals. We also offer free access to the Kidney Beam website (https://beamfeelgood.com/kidney-disease), whose mission is to help people living with kidney disease to feel good through movement, education and well-being support, for patients with impaired physical function.

The research team will review their symptom score results with participants and encourage them to discuss their results with their clinical team. The clinical team will also receive the output report when at least one domain score is flagged as moderate–severe concern as determined by established thresholds. Clinical teams will receive a list of potential management and referral options for patients flagged for moderate–severe concerns. Most notably, this study will be performed in collaboration with the non-malignant supportive-palliative care clinic at the Toronto General Hospital, which has been set up to address the supportive care needs of patients with chronic medical conditions, including kidney failure. Currently, two palliative care physicians, palliative care trainees and

a social worker provide services at this clinic. This clinic will be the primary referral suggestion for patients with significant symptom burden. However, decision about any symptom management interventions, including referral to the supportive care clinic or other specialty clinics (sleep clinic, pain clinic, medical psychiatry clinic, etc), will be left at the discretion of the main responsible clinical team.

At the end of the follow-up, all participants and nursing staff at the intervention site will complete an anonymous satisfaction survey including questions about acceptability, survey burden, relevance and importance. The staff satisfaction questionnaire will also ask about the intrusiveness of the procedures in their routine workflow. Responses will be scored on 5-point Likert scales (strongly agree, agree, neutral, disagree and strongly disagree).

Participants in the control arm will receive usual care. They will complete the same PROMIS-CATs as the intervention arm, but PROMIS-CAT scores will not be shared with participants nor with the clinical team.

This intervention is complex and involves an effort by both patients and the care team. While a future trial can establish effectiveness, various barriers may limit the integration of complex interventions into clinical care. As such, our pilot will include a preliminary process evaluation, which will also include collection of qualitative data in semistructured interviews. These interviews will be conducted with both patients and staff who participated in the pilot. The interview guide will include open-ended questions probing barriers and facilitators to implementation. Additional points of inquiry in these interviews include the perceived acceptability of the intervention, as well as the preferable and undesirable aspects of the intervention to inform necessary amendments to the interventions and study procedures ahead of the RCT.

Consenting participants in this pilot study will be asked if they are also interested in participating in these interviews. Participants who indicate an interest will be approached again at the end of the study to confirm their continued interest and to schedule an interview. Healthcare professionals involved in the pilot, including nephrologists, nurses and allied health professionals will also be identified and asked to participate in interviews. All interviews will occur at the convenience of participant and healthcare professionals, either by phone, video conference, or in a room in Toronto General Hospital. Each interview will be conducted by two researchers and audio recorded. The recordings will be transcribed, checked for accuracy and identifying information will be removed.

Data collection and measures used

Participants will complete PROMIS item banks using CATs to assess symptom severity, physical and social functioning.[52 53] PROMIS scores demonstrated excellent validity and reliability among patients with kidney failure.[13 57–59] Along with the PROMIS-CATs, additional PROMs will be administered at baseline and at the patient's final visit. Each PROMIS item bank is reported on a T-score metric. For symptom domains, a higher PROMIS T-score represents higher symptom severity and for function domains, lower scores represent lower functioning. PROMIS T scores are standardised to yield a mean score of 50, corresponding to the mean score of the U.S. general population, and a SD of 10 points.

The Kidney Disease Quality of Life—36 (KDQOL-36)[60 61] is a 36-item instrument that comprises four subscales including the generic core Short Form 12 (SF-12v1), and three kidney disease targeted domains: symptoms/problems, burden of kidney disease, and effects of kidney disease (8 items). SF-12v1 yields a mental component summary (MCS) and physical component summary (PCS) scores.[62] The raw numeric values of items in each subscale are transformed to a score from 0 to 100, with higher scores indicative of better HRQOL.[60 61] The MCS and PCS scores are subsequently converted to T-scores with a mean of 50 and an SD of 10.[60 61] KDQOL-36 has been validated in patients with CKD.[61]

The Edmonton Symptom Assessment System—Revised (ESAS-r)[8–11] assesses nine common symptoms such as pain, tiredness, drowsiness, nausea, lack of appetite, shortness of breath, depression, anxiety and well-being. The severity of each symptom is rated on a scale from 0 (absence of symptom) to 10 (worst possible severity). ESAS-r has been validated in patients with kidney failure on maintenance dialysis.[10 11]

The Social Difficulties Inventory (SDI)[7] is a self-reported 21-item instrument assessing the social impact of diagnosis and treatment (eg, domestic chores, personal care, available support). Initially developed for oncology practice, the SDI demonstrated good psychometric properties.[63 64] Response to items on the SDI range from 0 'no difficulty' to 3, 'very much difficult.' Its use in our patient population is supported by our preliminary findings.[64 65]

The EQ-5D-5L[66] is an instrument which measures HRQOL on five domains, including mobility, self-care, usual activities pain/discomfort and anxiety/depression, using one item per domain. Responses to each dimension is given in five levels: no problems, slight problems, moderate problems, severe problems and extreme problems. Its validity in assessing patients with CKD has been demonstrated.[57 66 67]

Self-reported sociodemographic characteristics including age, gender, educational level attained, employment status, marital status, ethnocultural background, income and postal code will also be collected. Clinical characteristics including laboratory results, comorbidity (evaluated using the Charlson Comorbiditiy Index),[2] aetiology and duration of kidney disease will be extracted from medical records using a standardised data extraction form.

The following information will also be collected from participants at each visit to assess for incidence of healthcare utilisation: any hospital or emergency admission within the previous 4 weeks, reason for healthcare use, dates of dialysis modality change or transplant, death or

Table 2 Summary of outcome measures to be assessed in the pilot study

Feasibility outcomes	Acceptability outcomes	Additional pilot outcomes
1. Recruitment target (30 in each arm of the study) reached by the end of month 3 2. Decline rate (eligible patients who decline participation) 3. Proportion of missed or refused PROM completions 4. Drop-out rate (death, transplant, dialysis modality change, loss to follow-up, withdrawal)	Proportion of patients who find the tool: 1. Acceptable 2. Not burdensome 3. Important (Patient Satisfaction Survey) 4. Proportion of staff who do not find the tool intrusive to workflow (Staff Satisfaction Survey)	Incidence rate of: 1. Hospitalisation 2. Emergency visits 3. Healthcare use (composite of above listed incidences) 4. Symptom burden, as assessed by i. ESAS-r: renal ii. Symptoms score from KDQOL-36 5. Quality of life, as assessed by the KDQOL-36 i. SF-12 PCS and MCS ii. Burden of kidney disease score from KDQOL-36 iii. Effect of kidney disease score from KDQOL-36

ESAS-r, Renal, Edmonton Symptom Assessment System-Revised: Renal; KDQOl-36, 36-item Kidney Disease Quality of Life Questionnaire; MCS, mental component score; PCS, physical component score; PROM, Patient-Reported Outcome Measure; SF-12, 12-item short-form survey; UHN, University Health Network.

moving to a different healthcare facility. This information will be cross referenced with hospital records.

Qualitative data from the semistructured interviews will be uploaded to Nvivo11 qualitative analysis software. The data will be analysed using a reflexive thematic analysis approach, with a focus on identifying themes that describe and facilitate understanding of the integration of ePROMs into clinical care. The process of coding and theme identification will be an iterative process, using both inductive and deductive approaches, involving immersion in the data, review of pertinent literature and reflection.

Data analysis

Data will be presented using appropriate descriptive statistics, including mean, SD, median, IQR, frequency and proportions. Four main feasibility outcomes will be reported (table 2). First, we will report the total number of participants recruited during the 3-month recruitment period. Second, we will compute the proportion of eligible patients (based on inclusion and exclusion criteria) who decline consent. Third, we will compute the completion rate, based on the proportion of missing or incomplete questionnaires. Lastly, we will report the drop-out rate due to any cause (death, transplant, dialysis modality change, loss to follow-up, withdrawal). Feasibility of the subsequent effectiveness trial will be confirmed if all four feasibility outcomes meet the following a priori criteria: (1) recruitment target of 60 participants (2) decline rate: < 50% (3) completion rate: > 80% of participants at least 50% of the time and (4) dropout rate less than 30%.

To assess acceptability, we will report the results of the satisfaction surveys, including the proportion of patients who find the tool (1) acceptable, (2) not burdensome (3) important based on responses to the 'Patient satisfaction survey' (table 2), and the proportion of staff who do not find (4) use of the tool intrusive to the workflow, based on to the Staff satisfaction survey. The intervention will be deemed acceptable if >80% of participants and staff answer positively to the acceptability questions. In addition, 4–5 participants and staff, who indicate their interest, will participate in semistructured interviews as part of the process evaluation. Participant interviews will be audiotaped, transcribed and deidentified. Two experienced qualitative researchers will independently code the transcripts based on preidentified coding categories, while allowing for new categories to be added.

The qualitative data from the semistructured interviews will be analysed using a content analysis approach to identify common patterns about perceptions, experiences, barriers, enablers and facilitators to sustainable implementation of this intervention.

In addition to acceptability, we will present a number of a pilot outcomes using descriptive statistics. These include quality of life scores, incidence of hospitalisation and incidence of healthcare use (table 2). No formal statistical analysis will be performed to compare these outcomes between the two study arms.

Data safety and monitoring

The use of a Data Safety and Monitoring Board (DSMB) was not applicable in the context of this study, given the explicit outcomes being explored, the small sample size and the non-invasive nature of the intervention. In the case where feasibility of an effectiveness trial is established in this pilot, a DSMB independent from the study sponsor and competing interests will be employed to both monitor study data and review interim analyses.

Trial status

Recruitment commenced in April 2023 and data collection is expected to finish in December 2023.

Ethics and dissemination

Consent process

The protocol was approved by the University Health Network Research Ethics Board (CAPCR #22-5199) and the William Osler Health System Research Ethics Board (#23-0005). Informed consent will be obtained from all those who agree to participate in the study.

Privacy

All researchers and staff will adhere to the principles in the Declaration of Helsinki. Each site will obtain approval from its Institutional Research Ethics Board. Data gathered on tablets and completed at home will be stored within secure firewalls and servers.

Dissemination

Results of this study will be shared with study participants, staff, healthcare professionals, researchers and relevant stakeholders. Results of the pilot will be published shortly after completion.

Results of this pilot study will inform the feasibility of a large, multi-centre RCT that will be conducted to assess the effectiveness of screening guided symptom management using the ePROMs assessment and response toolkit. This future trial will establish the clinical effectiveness of using this toolkit to reduce symptom burden and improve the HRQOL of patients on maintenance haemodialysis. This foundational work will also inform multiple future projects. Our study can be replicated in various geographical and population settings as well as in the care of other chronic disease.

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Contributors Study conception and design: JKG, MP, TA, IM. Drafting of the manuscript: JKG, MP, AS, TA, RS and IM. All authors contributed important intellectual content during manuscript drafting or revision and accepts accountability for the overall work by ensuring that questions pertaining to the accuracy or integrity of any portion of the work are appropriately investigated and resolved. Study supervision: IM. Final manuscript approval: all authors.

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Competing interests None declared.

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.

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