# *A study to assess the effect of physical therapy programme on QOL of patients with renal disease on hemodialysis in hospital*

**Manpreet Kaur Saggi[1], Charan Singh Poonia[2]**
[1]*Ph.D. Scholar, Department of Nursing, Desh Bhagat University, Mandi Gobindgarh, Punjab, India*
[2]*Professor, Desh Bhagat University, Mandi Gobindgarh, Punjab, India*

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**Abstract:**
**Background:** People living with advanced chronic kidney disease who receive maintenance haemodialysis commonly experience reduced exercise capacity, muscle weakness, fatigue, sleep disturbance, limitations in social and occupational roles, and substantial treatment-related burden. Quality of life is therefore an important outcome alongside biochemical control and dialysis adequacy. Structured physiotherapy may offer a practical way to address deconditioning, but benefits differ across populations and quality-of-life domains.
**Aim:** To assess the effect of a structured physical therapy programme on health-related quality of life among patients with renal disease receiving maintenance haemodialysis at DH Mohali.
**Design and proposed methods:** This manuscript presents a proposed quasi-experimental pre-test and post-test study with a usual-care comparison group. Eligible adults receiving stable maintenance haemodialysis would be assessed at baseline and after an eight- to twelve-week supervised programme. A kidney disease-specific quality-of-life measure. Functional capacity, fatigue, attendance, and exercise-related adverse events would be recorded as secondary outcomes. A final protocol should determine sample size from a prespecified primary outcome, confirm local feasibility, and obtain institutional ethics approval before recruitment.
**Expected contribution:** Evidence syntheses suggest that structured exercise may improve functional capacity and the physical component of health-related quality of life, although effects on mental health and several kidney-specific domains are less certain (Bernier-Jean et al., 2022; Greenwood et al., 2021). This study would provide local data on whether a supervised, individualised programme can be delivered safely and whether changes in quality-of-life scores are clinically meaningful in the participating dialysis unit.
**Reporting status:** No participants, study dates, ethics approval number, outcome scores, or statistical findings were supplied for this draft. Accordingly, this document is written as a research protocol manuscript and does not claim that the proposed study has been completed. The results section specifies what should be reported after real data have been collected and analysed.

**Keywords:**
Chronic kidney disease; haemodialysis; physical therapy; exercise rehabilitation; health-related quality of life; intradialytic exercise; KDQOL-36; quasi-experimental study.

## 1. Introduction:

Chronic kidney disease (CKD) is associated with a wide range of physical, psychological, social, and economic consequences. For people who progress to kidney failure and require maintenance haemodialysis, treatment is life sustaining but time consuming. Repeated journeys to a dialysis centre, several hours connected to a dialysis machine, dietary and fluid restrictions, medication schedules, vascular access care, and uncertainty about health can shape most aspects of everyday

life. The result is often a health experience that cannot be fully represented by laboratory values alone. Patient-reported health-related quality of life (HRQoL) helps describe how a person feels and functions within the realities of chronic disease and long-term treatment.

People receiving haemodialysis often report lower physical functioning than healthy people of a similar age. Walking, climbing stairs, carrying groceries, household work, leisure activities, and paid employment may become difficult as muscle strength and aerobic capacity decline. Fatigue can be present before dialysis, after treatment, or throughout the week. Common contributors include uraemia, anaemia, inflammation, inadequate nutrition, sleep disruption, pain, cardiovascular disease, diabetes, and physical inactivity. These factors interact rather than acting independently. Observational studies have associated greater physical activity with outcomes in dialysis populations (Stack et al., 2005), and exercise capacity has been associated with survival among ambulatory patients with kidney failure (Sietsema et al., 2004); neither association by itself proves that exercise training causes longer survival. A patient who becomes less active may lose muscle strength, which makes daily tasks more demanding, which in turn encourages further avoidance of movement.

The Kidney Disease: Improving Global Outcomes guideline recognises the relevance of physical activity and advises adults with CKD to undertake moderate-intensity activity for a cumulative duration of at least 150 minutes each week, or to a level compatible with cardiovascular and physical tolerance (KDIGO CKD Work Group, 2024). Such broad recommendations require individual adaptation for people who receive haemodialysis, particularly when patients have unstable cardiovascular conditions, symptomatic hypotension, frailty, or vascular access considerations. The goal is not to apply a standard exercise target indiscriminately, but to identify safe, achievable movement that can be sustained with clinical oversight.

Physical therapy can be delivered before, during, or between dialysis sessions. Intradialytic programmes have a practical advantage because patients are already present at the treatment centre and time spent in a seated or reclined position can sometimes be used for gentle movement. However, an exercise intervention is not simply a set of movements. It includes screening, consent, individual prescription, progressive loading, monitoring, documentation, patient education, and communication with the nephrology and nursing teams. The programme must accommodate symptoms, access type, and changes in fluid status, treatment schedules, and each patient's preferences.

Research on exercise in haemodialysis has grown over several decades, but the strength of evidence varies by intervention and outcome. Reviews commonly identify gains in walking ability and lower-limb function, while effects on generic and kidney-specific HRQoL vary between studies (Gomes Neto et al., 2018; Huang et al., 2019). The Cochrane review by (Bernier-Jean et al., 2022) found that exercise probably improves functional capacity and depressive symptoms, while the certainty of evidence for physical HRQoL was lower and the effect on the mental component remained uncertain. A local study should therefore measure outcomes directly rather than treating improved exercise performance as proof that every aspect of quality of life has changed.

This proposed study focuses on patients receiving haemodialysis at DH Mohali and centres on the patient-reported outcome of quality of life. It aims to combine a structured, progressive physiotherapy programme with a reproducible outcome assessment. By defining eligibility, intervention dose, safety procedures, and analysis before recruitment, the study can reduce ambiguity and make findings easier to interpret. A transparent protocol also separates the research plan from the results that must ultimately be generated by actual participant data.

## 2. Background and clinical significance:

Kidney failure affects multiple physiological systems. Loss of kidney function contributes to disturbances of fluid and electrolyte balance, anaemia, mineral and bone disorder, metabolic acidosis, and uraemic symptoms. Dialysis addresses important consequences of kidney failure but does not fully restore normal renal physiology. In addition, the treatment routine may reduce the time available for movement, employment, caregiving, education, or social participation. These

features make rehabilitation an important complementary component of person-centred kidney care rather than an optional extra.

The burden of haemodialysis is not evenly distributed. Age, frailty, diabetes, cardiac disease, peripheral vascular disease, neuropathy, depression, financial constraints, transport availability, literacy, and family support may all influence physical activity and perceived well-being. Some people are keen to exercise but have never received an individual prescription; others fear that movement may disturb the vascular access or cause a fall. Programme design must address both physiological risk and patient understanding. A person-centred explanation that validates concerns and shows how activity can be modified may improve confidence and participation.

The term quality of life covers physical functioning, emotional status, social participation, symptoms, treatment burden, and the person's own assessment of life circumstances. Generic instruments permit comparison across conditions, while disease-specific instruments ask about problems that matter especially to kidney patients. In haemodialysis, relevant experiences include restrictions caused by kidney disease, symptom burden, the perceived impact of treatment, and the time and energy required to manage the condition. A robust evaluation should avoid relying on a single global question when several domains may respond differently to rehabilitation.

Physical therapy may influence HRQoL through several pathways. Aerobic training may improve exercise tolerance, resistance work may help maintain muscle function, and repeated practice of functional movements may increase confidence in daily activities. Education and supervised success may reduce fear of movement and increase perceived control. Regular contact with a therapist can also identify barriers and facilitate referral for nutrition, mental health, pain, or occupational support. (Kouidi et al., 1997) examined psychosocial outcomes within renal exercise rehabilitation, underscoring that patient experience can extend beyond muscle performance. These are plausible pathways, not guaranteed outcomes; their presence and strength should be assessed in the setting being studied.

**3. Quality of life in people receiving haemodialysis:**

HRQoL is distinct from clinical status, although the two are related. A patient may have stable blood pressure and acceptable laboratory values yet still feel exhausted, isolated, unable to work, or dependent on family members for ordinary tasks. Conversely, a patient with several chronic diagnoses may rate some aspects of life positively because of supportive relationships, meaningful daily activities, or effective coping. Outcome measurement therefore asks about the patient's experience instead of assuming that clinicians can infer it from disease severity.

Physical HRQoL may be affected by limited mobility, muscle weakness, post-dialysis fatigue, breathlessness, pain, and reduced ability to perform household and community activities. The relationship between symptoms and activity can be bidirectional. Low activity contributes to deconditioning, while deconditioning makes activity feel harder. A programme that begins at a tolerable level and progresses gradually may help interrupt this cycle. Nevertheless, the intervention should not frame fatigue as laziness or assume that all fatigue is reversible through exercise; unexplained or worsening symptoms require clinical assessment.

Mental and social HRQoL can be affected by anxiety about prognosis, changes in family roles, restrictions on travel, dependence on regular treatment, employment difficulties, and concerns about body image or relationships. Physical rehabilitation may indirectly support these domains if patients feel more independent or are able to participate in activities they value. It should not be presented as a replacement for assessment and treatment of depression, anxiety, or social needs. The programme should include a referral pathway when patient responses indicate distress, safety concerns, or unmet support needs.

The KDQOL instrument was developed to combine a generic health survey with questions relevant to kidney disease and dialysis (Hays et al., 1994). The KDQOL-36 includes the physical and mental component summaries of the SF-12 together with scales addressing the burden of kidney disease, effects of kidney disease, and symptoms or problems. Its psychometric properties have been evaluated in large dialysis samples (Peipert et al., 2018). The version, language, scoring rules,

permission requirements, and local comprehensibility should be established before data collection, particularly where patients may prefer Punjabi, Hindi, or another language over English.

The generic SF-36 was developed to measure eight broad health concepts, including physical functioning, pain, vitality, social functioning, and mental health (Ware and Sherbourne, 1992). Generic measures support comparison across diseases but may not fully describe dialysis-specific burden. The KDQOL-36 is more focused but still cannot capture every individual priority. If resources allow, a brief patient interview can supplement the validated instrument without changing the standard questionnaire score. Such qualitative notes should be analysed transparently and not blended into numerical scales.

**4. Assessing patient-centred quality of life:**

A quality-of-life assessment should treat the participant as the expert on their own daily experience. The clinician can help the patient understand the questionnaire format, but answers should reflect the participant's own view. The illustrated domains are examples of concepts often relevant to kidney disease and are not a substitute for the formal items and scoring rules of the selected validated instrument.

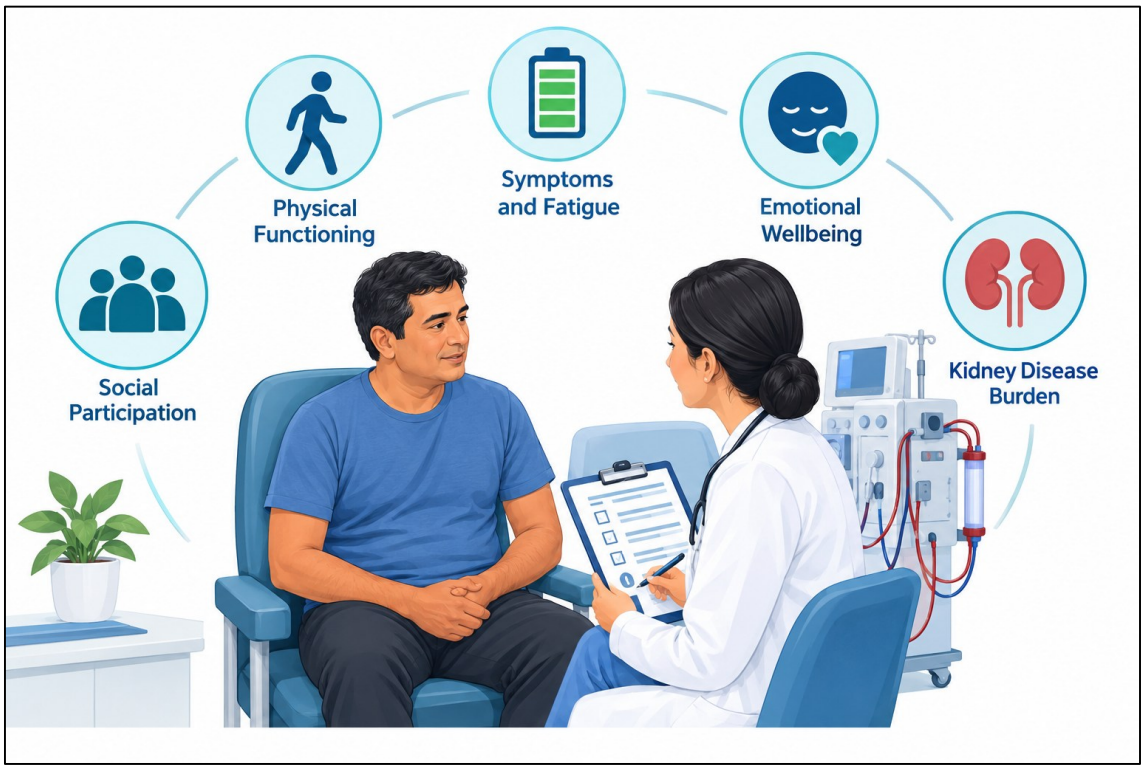



*Figure 1. Patient-centred assessment of quality-of-life domains relevant to kidney disease.*

**5. Physical inactivity, deconditioning, and renal disease:**

Reduced exercise capacity in kidney failure has several potential causes. Anaemia can reduce oxygen delivery; chronic inflammation and metabolic disturbances may contribute to muscle catabolism; neuropathy and vascular disease can limit lower-limb function; and comorbid cardiac or respiratory disease may increase exertional symptoms. Low protein-energy intake and frailty can further reduce strength. The resulting limitations can make activities of daily living more difficult even when the patient is medically stable enough to participate in low-intensity training.

Sedentary time during dialysis is substantial, but simply reducing seated time is not equivalent to a therapeutic exercise programme. Exercise should be planned to match the patient's current ability and clinical status, with a clear purpose, progressive but controlled loading, and a method for monitoring response. The World Health Organization's physical activity guidelines support regular movement and reduction of sedentary behaviour for adults, including people living with chronic conditions, while emphasising an approach that considers ability and context (World Health

Organization, 2020). In haemodialysis, translating these principles requires coordination with the treating team.

Intradialytic exercise commonly includes cycling, ankle and knee movements, light resistance exercise, or a combination of aerobic and resistance training. Interdialytic exercise may include walking, sit-to-stand practice, balance activities, and home-based exercises. There is no single programme suitable for every dialysis unit. Equipment availability, staffing, patient preference, the physical layout of the unit, and the clinical monitoring system should influence the final protocol. The present proposal places emphasis on supervised seated exercise, with additional functional activity only when individually assessed and cleared.

Muscle strengthening can be useful because lower-limb weakness often limits transfers, walking, and stair climbing. However, resistance should initially be low, movement should remain controlled, and the therapist should assess pain, joint problems, neuropathy, and balance limitations. Exercise involving the access arm must be determined by the treating clinician and the local vascular-access policy. As a precaution, the proposed intradialytic programme does not load or manipulate the arm containing an arteriovenous fistula or graft. Central venous catheter tubing must also remain secure and free from traction.

**6. Evidence from previous research:**

Johansen (2007) described the potential relevance of aerobic and resistance exercise for people with end-stage renal disease and highlighted the marked limitations in physical functioning observed in this population. The rationale for exercise is supported by physiological and observational evidence, but practical delivery in a dialysis environment requires more than extrapolation from healthy adults. A programme must account for the effects of dialysis timing, cardiovascular risk, symptoms, and clinical staffing, while distinguishing a structured intervention from general advice to be more active.

(Painter et al., 2000) evaluated exercise programming in haemodialysis patients and examined physical performance and self-reported health status. Their work illustrates why objective functional tests and patient-reported measures can be collected together: they answer related but different questions. An intervention may improve walking or sit-to-stand performance without producing a corresponding change in every HRQoL domain, particularly over a short period or when the questionnaire includes concerns not directly addressed by exercise.

(Manfredini et al., 2017) conducted a multicentre randomised trial of exercise in dialysis patients, contributing to the discussion about how exercise can be delivered and evaluated in real-world care. Their work and later implementation trials show that recruitment, adherence, patient preference, and delivery logistics are integral to intervention effectiveness. Even a physiologically sound programme can have limited impact if attendance is poor or the prescribed training is not delivered consistently. The proposed study therefore includes attendance and exercise fidelity as process outcomes rather than treating them as administrative details.

(Gomes Neto et al., 2018) reviewed intradialytic exercise training modalities and reported that combined aerobic and resistance exercise had favourable effects on several measures of physical function and selected HRQoL domains. (Huang et al., 2019) likewise found that exercise interventions may improve aerobic capacity, walking capacity, and HRQoL, while pointing to the need for careful programme design. These reviews support the premise of studying structured exercise, but heterogeneity in exercise dose, duration, participants, and outcome tools limits the transferability of any single pooled estimate to an individual dialysis unit.

(Zhao et al., 2019) synthesised randomised trials of exercise interventions in end-stage renal disease and reported improvements in fatigue, mood-related outcomes, physical activity, and quality of life across included studies. Interpretation should remain cautious because systematic reviews inherit the strengths and weaknesses of their primary studies. Small sample sizes, variation in comparator care, inconsistent intervention descriptions, and differences in follow-up timing can lead to uncertainty. A local evaluation should therefore prespecify a primary endpoint, use standardised scoring, document missing data, and report effect sizes with confidence intervals.

The review by (Gomes Neto et al., 2018) and the earlier synthesis by Cheema and Fiatarone Singh (2005) support the use of functional outcome measures that are feasible in routine practice. A six-minute walk test, timed sit-to-stand test, gait assessment, or a grip-strength measure may help establish whether exercise produces a functional change. Selection should depend on medical stability, space, mobility, and staff training. If the primary study is centred on HRQoL, functional measures should be secondary outcomes rather than substitutes for the quality-of-life endpoint. Tests should be conducted in a consistent relation to the dialysis schedule to reduce measurement variation.

The 2021 systematic review and meta-analysis by Zhang et al. on intradialytic resistance exercise reported improvements in some physical performance measures, while finding no significant improvement in pooled quality-of-life outcomes. This contrast is important: improved muscle function does not automatically mean that patients perceive broad changes in life quality. A person can become stronger but still have treatment-related restrictions, comorbid symptoms, or psychosocial stressors. The intervention and measurement strategy should be aligned with the precise question being asked.

A broader Cochrane review by (Bernier-Jean et al., 2022) included 89 studies and 4,291 participants receiving dialysis. It concluded that exercise training probably improves functional capacity and depressive symptoms, and may improve physical HRQoL, but uncertainty remained regarding mental HRQoL and safety outcomes. The authors noted low certainty for some outcomes and diversity in exercise programmes. These conclusions support a cautious, outcomes-focused approach. They do not justify promising participants that exercise will necessarily improve all domains, prevent cardiovascular events, or change survival.

The PEDAL randomised trial by (Greenwood et al., 2021) examined an intradialytic exercise programme designed to improve quality of life among people receiving haemodialysis. Its importance lies not only in outcome results but also in the challenges of implementing a programme within busy dialysis services. Exercise dose received, participant engagement, and practical barriers can differ from the protocol dose. Evaluations should report adherence and fidelity alongside the primary outcome to help explain why an intervention did or did not achieve the intended effect in a particular setting.

Evidence is not uniformly positive. The systematic review of intradialytic exercise safety and efficacy published in BMJ Open found improvements in some depression and physical HRQoL outcomes, but also reported heterogeneity and limitations in the available trials (Pu et al., 2019). The intradialytic cycling review by Greenwood and colleagues in Nephrology Dialysis Transplantation found clearer benefit for six-minute walking distance than for several pooled cardiovascular or generic HRQoL outcomes. Segura-Ortí (2010) similarly emphasised that structured exercise is relevant to physical and psychological deconditioning in haemodialysis, while noting the limitations of the evidence base. These mixed findings support measuring several related outcomes while keeping the primary question focused and avoiding selective reporting.

Taken together, the literature gives a reasonable basis for a carefully supervised programme but does not remove the need for setting-specific evaluation. The proposed work is not a systematic review and will not independently estimate an overall treatment effect from published trials. Instead, it would assess whether a defined programme can be implemented at the named site and examine change in a prespecified quality-of-life measure. Literature findings inform the hypothesis and design; they must not be written as if they were results from patients recruited at DH Mohali.

### 6.1. Research gap and rationale:

Although exercise interventions have been studied in dialysis populations, practical programmes differ greatly in equipment, staff training, duration, intensity, frequency, progression, and the amount of supervision. Some interventions use only cycling, some use resistance exercise, and others include walking or home-based activity. This makes it difficult for a local unit to know which components are feasible and which outcomes should be expected. A clearly described

programme can add value by documenting the activities delivered and the response of patients in a particular clinical environment.

Another gap concerns measurement. Studies may use generic instruments, kidney-specific questionnaires, fatigue scales, or physical performance tests. These tools capture different constructs, and a change in one does not guarantee change in another. A study whose main purpose is quality of life should use a validated patient-reported outcome as the primary measure, administer it consistently, and avoid creating an unvalidated composite from unrelated scales. Functional testing can complement the primary measure and may help explain how a perceived change occurs.

A structured programme may also help identify operational barriers relevant to Indian dialysis services, including travel distance, treatment timing, family responsibilities, financial limitations, language preference, and differences in baseline activity. Local feasibility cannot be inferred solely from studies conducted elsewhere. Recruitment rate, attendance, reasons for missed sessions, exercise modifications, and adverse events are useful data because they demonstrate whether an intervention could be integrated into routine care. These process measures are particularly important when the study uses a quasi-experimental design rather than individual randomisation.

The rationale for the proposed study is therefore threefold: to assess pre-to-post change in HRQoL; to examine whether any change differs from usual care over the same observation period; and to evaluate the feasibility and safety of supervised physiotherapy in the dialysis setting. An appropriate interpretation would consider both statistical uncertainty and the size and meaning of changes to patients. It would also acknowledge that a single-centre quasi-experimental design cannot establish the same level of causal certainty as a well-conducted multicentre randomised trial.

## 7. Aim of the study:

To assess the effect of a structured physical therapy programme on health-related quality of life among patients with renal disease receiving maintenance haemodialysis at DH Mohali.

**Specific objectives:**

The study would be guided by the following objectives:

- To assess baseline health-related quality of life among eligible patients receiving maintenance haemodialysis.
- To implement a structured, individualised physical therapy programme under clinical supervision for the intervention group.
- To compare post-intervention quality-of-life scores with baseline scores within the intervention group.
- To compare change in quality-of-life scores between the intervention group and the usual-care comparison group over the same period.
- To examine changes in functional capacity and fatigue, where feasible and appropriate for participants.
- To document attendance, adherence, reasons for missed sessions, programme modifications, and exercise-related adverse events.
- To explore whether age, duration of dialysis, comorbidities, baseline functional status, or other prespecified characteristics are associated with response to the programme, subject to the final sample size.

## 8. Research questions and hypotheses:

The primary research question is whether a structured physical therapy programme produces a greater improvement in HRQoL than usual care among people receiving maintenance haemodialysis at the study site. Secondary questions concern changes in functional capacity and fatigue, as well as the feasibility of integrating supervised exercise into the dialysis schedule.

The null hypothesis is that the mean change in the prespecified primary HRQoL score does not differ between the physical therapy group and the usual-care group over the intervention period. The alternative hypothesis is that the mean change differs between groups. If the final protocol is designed to test a directional hypothesis, the direction must be justified in advance; however, two-

sided testing is generally appropriate because deterioration, no change, or improvement may all be plausible in a medically complex population.

The primary outcome and its scoring method must be fixed before enrolment. If the KDQOL-36 physical component summary is selected as the primary endpoint, the study must not switch to a different subscale after looking at the data merely because that subscale gives a more favourable result. A limited set of prespecified secondary outcomes is preferable to a long list of exploratory comparisons. This protects against selective analysis and makes the final conclusion easier to interpret.

## 9. Conceptual framework:

The conceptual model proposes that structured physical therapy may influence HRQoL through changes in muscle strength, movement tolerance, aerobic endurance, confidence, perceived control, and participation in daily activities. These intermediate changes may reduce the effort required for tasks such as transferring from bed to chair, walking short distances, or performing household work. Patients may then perceive improved independence and physical well-being. Each link is plausible, but the study should measure these constructs separately where possible and should not assume that all changes occur in every participant.

The relationship may be modified by baseline function, anaemia, cardiovascular disease, diabetes, nutrition, depression, pain, age, dialysis vintage, family support, and the dose of exercise actually completed. Some factors, such as baseline disease severity, may be confounders in a non-randomised comparison. Others, such as adherence, may sit on the pathway between being offered the programme and experiencing an outcome. The analysis plan should identify key covariates before the dataset is examined and should be cautious about adjusting for variables that are consequences of the intervention.

The framework also recognises that quality of life is multidimensional. A physical therapy programme is most directly expected to influence physical functioning and perceived physical health. It may affect social or emotional domains indirectly, but these outcomes depend on relationships, finances, mental health, treatment burden, and other circumstances. Accordingly, a modest or absent change in a mental-health scale would not necessarily mean that physical therapy failed to improve walking or strength. Equally, improved test performance should not be used to claim a broad improvement in life satisfaction if the patient-reported outcome does not support that conclusion.

### 9.1. Proposed methodology:

This manuscript describes a proposed protocol. Before it is used as an actual study report, the investigator must replace proposed language with the verified details of the study that was approved and performed. Dates, sample size, recruitment method, instrument version, intervention dose, eligibility decisions, protocol deviations, and analysis decisions must match the research records. The site name is reproduced as provided in the title; investigators should use the institution's formally approved name in ethics documents and the final paper.

### 9.2. Study design:

A quasi-experimental pre-test and post-test comparison-group design is proposed. Participants allocated to the intervention group would receive the physical therapy programme in addition to usual haemodialysis care. Participants in the comparison group would continue usual care over the same period. Outcomes would be measured at baseline and at the end of the programme, with a follow-up assessment if feasible. This design is practical when individual randomisation is difficult, but it carries a risk of selection bias and residual confounding. If the service and resources permit, a randomised controlled design would strengthen causal inference.

The assignment process must be described transparently. If group assignment is based on dialysis shift, availability, patient preference, or another operational consideration, the reason should be documented and its potential association with outcomes discussed. The groups should be recruited

from the same service and calendar period where possible, so that staffing, seasonal effects, dialysis policies, or other service changes do not systematically affect one group more than the other. Allocation should not be altered based on a participant's apparent likelihood of improvement.

The study should be registered prospectively if required by the institution, ethics committee, funding body, or target journal. The protocol should define one primary outcome, the assessment time point, eligibility criteria, intervention components, and planned statistical analysis before recruitment. A protocol amendment should be dated, justified, and approved where necessary. Prospective documentation reduces the temptation to change outcomes or methods after results become known and gives readers a basis for judging the credibility of the report. Development and evaluation can also be informed by guidance for complex interventions, including attention to implementation and context (Craig et al., 2008).

**9.3. Study setting:**

The proposed setting is the haemodialysis unit at DH Mohali, as specified in the title. The final protocol should describe the number of dialysis stations, usual treatment schedule, staffing arrangements, availability of a physiotherapist, and the local procedure for medical review before exercise. It should also identify whether the programme is to be delivered during dialysis, between treatments, or in a combination format. These operational details affect feasibility and should be stated sufficiently clearly for another centre to understand how the intervention was implemented.

Before recruitment, the research team should complete a walk-through of the treatment area and map the space needed for the proposed movements and equipment. The dialysis nurse should be able to observe access lines and the patient's condition without obstruction. Exercise materials should be cleaned according to local infection-prevention procedures, and equipment should not obstruct emergency access. A named clinician should be responsible for deciding when a patient's medical status makes exercise inappropriate on a particular day.

**9.4. Eligibility criteria:**

Suggested inclusion criteria are: adults aged 18 years or older; a documented diagnosis of advanced kidney disease requiring maintenance haemodialysis; a stable dialysis schedule for a prespecified period; ability to understand study information and provide informed consent; and medical clearance for low-intensity physical activity. The local team may choose a minimum dialysis vintage, for example three months, to reduce inclusion of people still adapting to treatment, but that threshold should be justified and kept consistent.

Suggested exclusion or temporary-deferral criteria include an acute medical event, unstable angina or another unstable cardiovascular condition, uncontrolled symptomatic arrhythmia, severe breathlessness at rest, acute infection with systemic symptoms, recent major surgery, active musculoskeletal injury that prevents the movements, severe cognitive impairment that prevents informed consent, or a treating clinician's judgment that exercise is unsafe. These criteria should be adapted to clinical policy and not applied as a substitute for individual review. Frailty or older age alone should not automatically exclude a patient if safe activity can be adapted.

Patients with an arteriovenous fistula or graft require specific access precautions. The exercise programme should avoid pressure, traction, vigorous movement, or resistance applied to the access limb unless the treating team has explicitly assessed and approved an activity. The dialysis line and catheter should remain secured and visible. Any new bleeding, access pain, swelling, or disruption requires immediate cessation and clinical assessment. Written procedures should be available to the physiotherapist and dialysis nurses.

**9.5. Sample size and sampling approach:**

The final sample size should be calculated from the planned between-group difference in the primary HRQoL score, the expected standard deviation, the selected type I error, desired statistical power, and anticipated attrition. If no sufficiently comparable local estimate is available, a small pilot or a carefully justified estimate from a relevant published trial may be used. A statement such

as “sixty patients were selected” is not enough: the manuscript should show the assumptions used and explain how many participants are required in each group. The sample-size calculation should not be retrofitted after observing the results.

For planning purposes, the investigator may compare a sample size derived from an independent two-group comparison with one derived from a baseline-adjusted model, because the latter can be more efficient when baseline and follow-up scores are correlated. The statistician should consider unequal group sizes, clustering by dialysis shift if relevant, and loss to follow-up. The proposed programme may be feasible with a smaller sample, but feasibility objectives should be distinguished from a definitive hypothesis test. If recruitment is limited, confidence intervals and transparent discussion of precision are especially important.

The sampling method should reflect the actual process. Consecutive sampling means inviting all eligible patients in sequence. Convenience sampling means recruiting those who are readily available or willing. Neither approach guarantees that the enrolled participants represent all patients receiving dialysis at the centre. A flow diagram and description of non-participation can help readers judge selection bias. If the final project uses a different sampling procedure than the one proposed here, the methods must be revised accordingly.

### 9.6. Variables and operational definitions:

The independent variable is participation in the structured physical therapy programme in addition to usual haemodialysis care. The primary dependent variable is change in the selected HRQoL score between baseline and post-intervention assessment. Secondary dependent variables may include a standardised measure of functional capacity, fatigue, session attendance, adherence to prescribed exercise dose, and adverse events. Potential confounders include age, sex, baseline HRQoL, dialysis vintage, comorbidity burden, vascular access type, baseline functional capacity, and major changes in clinical status during the study.

Quality of life should be defined operationally through the exact validated questionnaire selected for use. For the KDQOL-36, scoring must follow the relevant manual and version. Scale scores should be transformed and interpreted according to the instrument instructions; higher scores typically indicate better health status for KDQOL-36 scales, but staff should verify the scoring rules for each scale and handle missing items in accordance with the manual. Unapproved changes to wording or scoring can undermine comparability and validity.

Functional capacity should be measured with a test that is safe and feasible in the dialysis unit. The six-minute walk test is useful where a measured corridor and trained staff are available, while a timed sit-to-stand measure may be more practical for some patients. Test instructions, footwear, assistive device use, encouragement, rest periods, and relation to the dialysis session should be standardised. The same protocol should be used at baseline and follow-up. Participants with contraindications should not be forced to complete a test solely to avoid missing data.

An adverse event is any unwanted medical occurrence during or shortly after a study exercise session, whether or not it is ultimately attributed to exercise. Events of interest may include symptomatic hypotension, chest discomfort, new severe dyspnoea, dizziness, syncope, unusual palpitations, access bleeding, musculoskeletal pain, falls, or line complications. Severity, timing, action taken, outcome, and the investigator’s assessment of relatedness should be documented. An absence of reported events should not be interpreted as proof of safety if monitoring or reporting was incomplete.

### 9.7. Physical therapy programme:

The programme should be written as an intervention manual rather than a general intention to “provide physiotherapy.” A proposed starting framework is an eight- to twelve-week course, with supervised sessions two or three times weekly, ideally coordinated with the regular dialysis schedule. The exact duration and frequency should be agreed with the unit, informed by feasibility, and finalised before recruitment. Evidence from clinical trials includes programmes ranging from

weeks to months, often delivered three times weekly, but no single duration has been established as optimal for every patient (Bernier-Jean et al., 2022).

Each session should begin with a brief safety screen and warm-up. The physiotherapist or trained study clinician should ask about intercurrent illness, chest symptoms, dizziness, falls, unusual muscle pain, recent access problems, and changes in medication or clinical condition that may affect exercise tolerance. Blood pressure, pulse, symptoms, and other observations should be recorded according to local policy. When observations are outside the unit's agreed limits or the patient is symptomatic, exercise should be deferred pending appropriate clinical review.

A gentle warm-up may include diaphragmatic breathing without straining, ankle pumps, alternating heel lifts, comfortable knee extension, and small-range shoulder movement that does not stress vascular access. Movements should be smooth and pain free. The patient should be positioned comfortably, with access lines visible and protected. The warm-up is also an opportunity to reassess the patient's coordination, comfort, alertness, and willingness to continue that day. It is acceptable to shorten or omit a session when the clinical condition warrants it.

The aerobic component may use a bedside pedal exerciser or another approved low-impact method where equipment is available. Intensity should begin at a light level and progress only when the participant can speak comfortably and complete the movement without concerning symptoms. A perceived exertion scale can support individual titration, but it should not replace monitoring of symptoms and clinical observations. Duration might progress in short blocks rather than requiring every participant to complete the same number of minutes from the first session.

Resistance exercises may include repeated sit-to-stand practice when safe, knee extension, heel raises, ankle dorsiflexion, or gentle lower-limb resistance using a light band. The selection should be based on baseline strength, joint health, neuropathy, balance, and access precautions. Patients should breathe continuously and avoid breath-holding or forceful straining. Exercise resistance should be recorded and progressed gradually using a written rule, such as increasing repetitions before resistance when movements are completed with good technique and no adverse symptoms.

Functional training should focus on activities relevant to the patient's life. For a patient who has difficulty rising from a chair, supported sit-to-stand training may be more meaningful than a generic exercise set. For someone who feels unsteady, balance and transfer assessment outside the dialysis treatment may be more suitable than intradialytic standing. Patients who have high fall risk should not perform unsupported standing exercises beside the dialysis chair. Functional work that requires moving away from the machine should occur only when the dialysis team considers the timing and disconnection process safe.

The cool-down should use gentle movement and a gradual return to rest. The clinician should check symptoms and repeat observations according to the protocol. Patients should be asked whether they felt chest discomfort, breathlessness beyond the expected level, dizziness, cramps, pain, unusual fatigue, or anxiety during the session. If any symptom is present, the team should follow local medical escalation procedures. Advice after the session should reinforce hydration and fluid intake instructions from the renal team rather than providing generic fluid advice that might conflict with the patient's prescription.

Education should explain the goals of exercise, expected mild muscular effort, warning symptoms, and the difference between manageable effort and danger signs. Patients should be encouraged to report concerns rather than hide symptoms to avoid disappointing the therapist. Written or pictorial material should be available in a language they understand. Family involvement may support home adherence when the participant wishes it, but family members should not pressure patients to exercise when they are unwell. The intervention should maintain autonomy and avoid blaming patients for missed sessions.

Progression should be guided by function and clinical response, not by a fixed calendar alone. If a patient completes the session comfortably and recovers without concerning symptoms, the therapist may gradually extend movement time or increase repetitions. If symptoms worsen, intensity should be reduced or the session paused while the cause is evaluated. Dialysis-day variation is expected, and prescribed exercise may need to be modified in response to fluid removal, sleep, pain, blood pressure, intercurrent infection, or changes in treatment.

Intervention fidelity should be documented. The session record should specify the exercises actually completed, duration, perceived exertion, rest breaks, assistance provided, any change from the protocol, and reason for modification. This information helps interpret a null result: the planned intervention may be ineffective, or the dose received may have been too small. It also helps recognise whether some components were difficult to deliver within routine haemodialysis care. Protocol fidelity should be reported without penalising reasonable clinical adaptations.

### 9.8. Proposed intervention dose and progression:

The table below is a planning framework and must be adapted and approved by the treating team before implementation. It is not a prescription for an individual patient and should not replace clinical clearance.

*Table 1. Proposed intervention dose and progression*

| Component | Proposed activity | Progression / dose | Safety and documentation |
|---|---|---|---|
| Pre-session screen | Symptoms, clinical status, access/line security, and observations per local policy. | Before each session; defer if unstable or symptomatic. | Document clearance, deferral, and clinician contacted. |
| Warm-up | Ankle pumps, heel raises, comfortable knee extension, relaxed breathing. | About 5 minutes, adjusted to tolerance. | No straining; keep lines visible and access protected. |
| Aerobic work | Seated low-impact cycling or approved repeated lower-limb movement. | Begin with short bouts; build gradually toward 10–20 minutes if appropriate. | Light-to-moderate effort only; monitor symptoms and exertion. |
| Resistance work | Low-resistance knee extension, heel raise, ankle movements, or light band work. | One to two sets of comfortable repetitions; progress repetitions before resistance. | Avoid loading the access arm; stop for pain or unusual symptoms. |
| Functional training | Supported sit-to-stand or mobility task outside dialysis when separately cleared. | Individualised task practice on appropriate days. | No unsupported standing beside connected dialysis equipment. |
| Cool-down | Slow movement, comfortable rest, symptom check. | About 3–5 minutes. | Record recovery and any adverse event. |
| Adherence / review | Session attendance, exercise dose, perceived exertion, modifications. | Review weekly and adjust according to response. | Document actual dose received, not only planned dose. |

### 9.9. Safety screening and clinical monitoring:

Exercise during dialysis must be subordinate to the safety of haemodialysis treatment. The dialysis nurse and treating clinician retain responsibility for dialysis-related care; the physiotherapist should not alter ultrafiltration, dialysate prescriptions, medication, or vascular-access management. The potential effects of intradialytic movement on haemodynamic stability and cardiac stress have been explored, but those findings do not remove the need for individual screening and clinical monitoring (McGuire et al., 2021). A clear division of responsibilities reduces confusion when

symptoms arise. The unit should identify the clinician who can promptly assess a patient who develops chest pain, acute breathlessness, syncope, symptomatic hypotension, persistent tachycardia, new neurological symptoms, or access complications.

Screening thresholds should be specified by the local nephrology team rather than invented as universal values in a research manuscript. Blood pressure that is unusually low or high for the participant, a marked change from baseline, fever with systemic symptoms, new oxygen requirement, unstable rhythm, or significant fluid-related symptoms may prompt deferral. A participant who is not suitable for exercise on one day may remain enrolled if the problem resolves and the clinical team confirms readiness. Repeated deferral should prompt review of the programme's suitability and the patient's goals.

An intradialytic programme should generally be positioned to reduce interference with the early haemodynamic changes associated with fluid removal. The precise start time should be established locally, taking into account dialysis prescription and medical advice. The exercise period should not coincide with procedures, meals if they create discomfort, medication administration requiring rest, or times when the patient is clinically unstable. Staff should be able to stop the exercise immediately without pulling on tubing, displacing needles, or obstructing access to the patient.

A stop rule should be written in plain language and displayed where relevant. Exercise should stop immediately if the participant requests it or develops chest pain, unusual shortness of breath, severe dizziness, near-syncope, new palpitations, acute confusion, access bleeding, tubing displacement, significant pain, or a clinically concerning change in observations. The patient should be assessed and treated according to clinical policy. Recommencement should occur only after the responsible clinician has reviewed the event and determined that it is appropriate.

Documentation must be timely and factual. The record should include the observed symptom, relevant vital signs, intervention stopped, clinical response, people notified, treatment provided, and follow-up plan. Serious or unexpected events should be reported to the investigator, ethics committee, or sponsor according to local policy. The report should not assume causation without review, but it should not omit an event simply because the participant had multiple comorbidities. Safety reporting is essential for a balanced interpretation of programme feasibility.

Exercise may be inappropriate on some treatment days because of infection, poor sleep, severe fatigue, recent falls, pain, medication changes, or unstable observations. A flexible protocol should distinguish a temporary missed session from withdrawal from the study. Reasons for missed sessions can reveal barriers that might be addressed through a modified schedule or lower initial dose. The participant should retain the right to stop exercising or withdraw from research without affecting access to dialysis or standard care.

### 9.10. Outcome measures and data collection:

Baseline assessment should be completed before the first exercise session and after consent. It should include demographic variables relevant to the research question, dialysis history, clinical characteristics permitted by the approved protocol, baseline HRQoL, and the selected physical function assessment. Information should be limited to what is necessary to answer the study question. Collection of excessive personal information adds burden and increases privacy risk without necessarily improving the analysis.

The KDQOL-36 is a suitable candidate for the primary HRQoL measure because it includes generic physical and mental health summaries alongside kidney-specific scales (Hays et al., 1994; Peipert et al., 2018). The study team should use the appropriate version and validated language, follow instructions for administration and scoring, and maintain any required permission or licensing conditions. If a translation is needed, investigators should use an existing validated translation rather than improvising new wording during data collection. Interview administration may be considered for patients with reading difficulties, but the same method should be used consistently where possible.

The questionnaire should be administered in a private and respectful manner. Participants must be told that there are no correct or incorrect answers and that responses will not determine their access to treatment. Staff should not coach a patient toward favourable answers or suggest that exercise

ought to improve the score. Participants should be allowed adequate time and may request clarification about the response format without having the question reinterpreted. Any missing response should be handled according to the scoring manual and recorded in the dataset.

Functional assessment may include the six-minute walk test, timed sit-to-stand test, gait speed, or another validated measure selected before recruitment. The same assessor, instructions, equipment, test location, and timing relative to dialysis should be used wherever practical. If multiple tests are selected, the protocol should define the order and rest interval. The test should be terminated when clinical symptoms or safety criteria require it. An inability to complete a test is itself relevant clinical information and should be recorded rather than coded as zero performance unless that is the validated scoring method.

Fatigue can be assessed with a validated short scale if fatigue is a prespecified secondary outcome. The instrument should be selected with attention to language validity, respondent burden, and interpretation. Fatigue varies across the dialysis cycle, so the assessment time needs to be standardised. Patients should be asked not to compare only their best or worst day with the whole previous month unless the instrument specifically requests that recall period. An appropriately recorded symptom score can help contextualise functional and HRQoL changes.

**10. Data analysis plan:**

The analysis should be completed according to a dated statistical analysis plan. Continuous variables should be summarised using mean and standard deviation when their distribution is reasonably symmetric, or median and interquartile range when skewed. Categorical variables should be summarised as counts and percentages. Baseline characteristics should be described by group to show the degree of similarity and potential imbalance; significance tests of baseline differences should not be used as a gatekeeper for selecting covariates.

The principal analysis should compare the groups' post-intervention primary HRQoL scores while accounting for baseline scores, or compare group changes using a prespecified model appropriate to the design and distribution of the data. An analysis of covariance model may be useful when assumptions are met, because it adjusts for the baseline value. If participants are measured at more than two time points, a mixed-effects model may account for correlation within participants and unequal numbers of observations, provided the sample size and data support its use. The statistician should state the chosen method and assumptions before examining treatment effects.

Effect estimates should be reported with 95% confidence intervals and exact p-values, rounded appropriately. Statistical significance alone does not establish clinical importance. The report should consider the magnitude of the score difference, direction, confidence interval, and any published guidance on meaningful change for the selected instrument and population. If there is no well-established minimal important difference for the local version, the limitation should be acknowledged rather than creating an unsupported threshold after data collection.

Potential confounding is particularly important in a quasi-experimental study. If groups differ in baseline function, age, comorbidity, dialysis vintage, or motivation, their outcomes may differ for reasons other than exercise. A small sample cannot reliably support adjustment for many variables, so the covariate set should be clinically justified and parsimonious. The analysis should avoid interpreting a complex adjusted model as definitive when estimates are unstable. Propensity methods or weighting should be considered only if sample size and data quality are adequate and the methods are prespecified.

Missing outcome data should be described by group, measure, and reason where known. The analysis should follow the instrument's scoring instructions and the study's prespecified missing-data approach. Complete-case analysis can be biased when missingness relates to health status or adherence. Multiple imputation may be considered if assumptions and sample size support it, but imputation should not be used mechanically. Sensitivity analyses should examine whether conclusions change under plausible assumptions about missing outcomes.

The primary analysis should follow the group assignment defined at enrolment whenever possible, while adherence-based analyses may be presented as secondary and clearly labelled. Excluding

participants who attended few sessions can overestimate benefit because adherence may be associated with baseline health, family support, motivation, or symptom burden. A per-protocol analysis should therefore not replace the principal analysis without explanation. The report should state how withdrawals, protocol deviations, and participants with incomplete data were handled.

Secondary outcomes should be interpreted cautiously, particularly if several domains are examined. A multiplicity adjustment may be appropriate when multiple confirmatory outcomes are specified; alternatively, the protocol can define secondary analyses as exploratory. Subgroup analyses by age, sex, diabetes, dialysis duration, or baseline function should be limited and based on prespecified hypotheses. Small subgroups lead to imprecise estimates and should not be used to make strong claims about which patients benefit most.

Analyses should be performed using recognised statistical software, with the version recorded. The protocol should identify the statistical support available and the person responsible for validating the analysis. Where possible, tables should report denominators for every percentage and explain any difference in denominators. Graphs of individual baseline and follow-up scores can reveal heterogeneity and help avoid over-reliance on group averages. All analyses should be reproducible from a locked dataset and documented code or syntax.

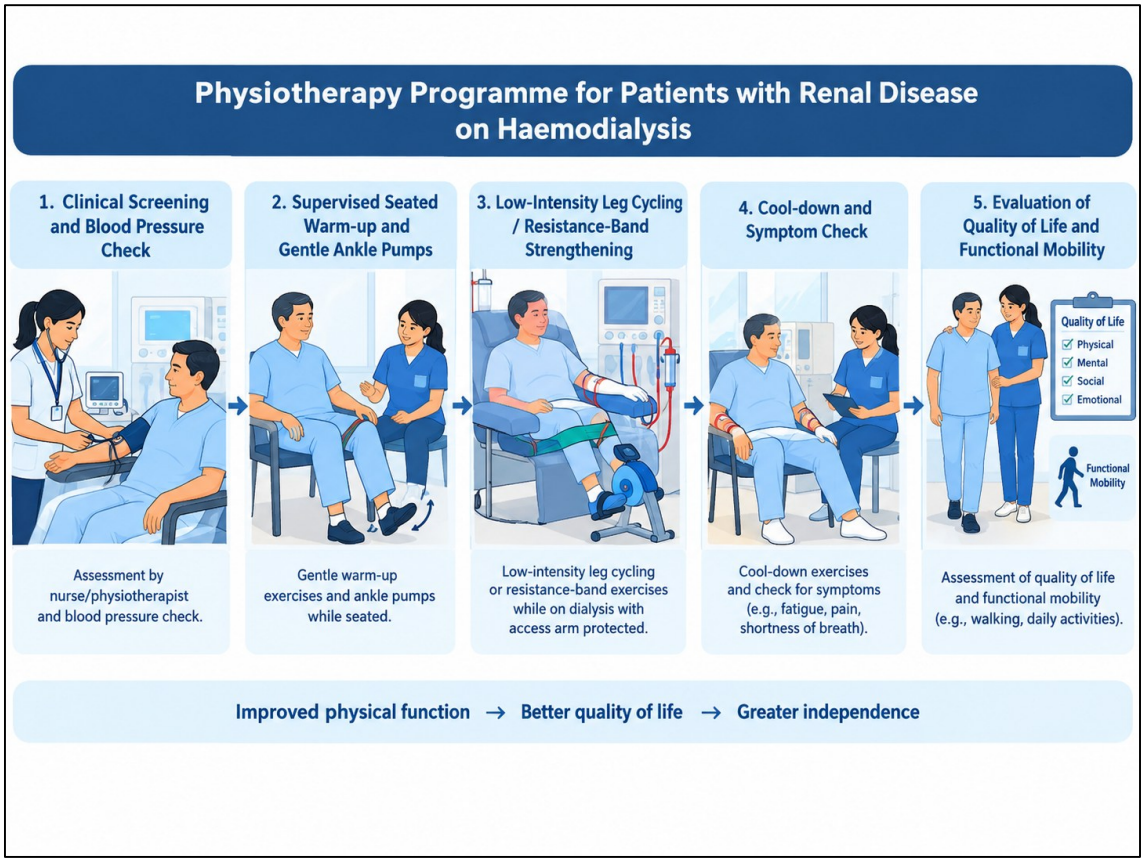



*Figure 2. Proposed pathway for screening, supervised exercise, monitoring, and outcome assessment*

**11. Ethical considerations:**

The proposed study must receive approval from the appropriate institutional ethics committee before participants are approached for research procedures. The approval number, approval date, and any required registration details must be added to the final report from the official documentation. This draft does not assert that approval has been granted. If the study has already been performed, the investigators should verify that approval preceded recruitment and that the activities conducted matched the approved protocol.

Informed consent should be obtained in a language the participant understands. The information sheet should explain the study purpose, expected time, exercise activities, possible discomforts and

risks, likely benefits, confidentiality measures, voluntary nature of participation, and right to withdraw without loss of clinical care. Participants should have the opportunity to ask questions and should not feel pressured by staff who control access to routine treatment. Consent should be documented according to institutional policy. The study must use proportionate safeguards because patients receiving dialysis may feel dependent on the clinical team. Recruitment should make clear that declining exercise research will not affect treatment scheduling, dialysis quality, staff attitudes, or eligibility for other services. Researchers should avoid implying that participation is necessary to receive good care. If the treating clinician is also a member of the research team, additional steps may be needed to minimise perceived coercion. Confidentiality should be protected through coded study identifiers, restricted access, secure storage, and reporting of aggregated results. Direct identifiers should not be included in the analytical dataset or circulated in routine project files. Photographs or video recordings of patients should not be taken for publication without separate informed consent and institutional approval. The illustrative images included in this manuscript are not actual participants and must not be presented as clinical evidence or as a visual record of study conduct.

Risk minimisation includes individual medical clearance, access precautions, monitoring, stop rules, staff training, and a process for responding to adverse events. The patient's usual clinical care takes priority over research activities. Participants should not be asked to continue despite symptoms for the sake of completing a session. Any compensation for time, travel, or expenses should be disclosed and approved as required; it should not be so large that it undermines voluntary consent.

The final publication should state funding, conflicts of interest, data availability, author contributions, and any role played by the institution or sponsor. Authors should not claim that a physiotherapy programme is safe or effective solely because it is described in the protocol. Reporting should follow an appropriate guideline for the final design, such as relevant guidance for non-randomised intervention studies or trial protocols. Ethical transparency is a requirement of research integrity rather than a formality added at submission.

## 12. Planned presentation of results:

Because no primary dataset was provided, there are no empirical results to report in this draft. The final completed manuscript must replace this section with observed findings, based on the approved study and locked dataset. Numbers must not be estimated from the literature, invented to make the article appear complete, or copied from another trial as if they belonged to DH Mohali. Published effect estimates are contextual evidence only and should remain attributed to their original studies.

The first results table should describe participant flow: screened, eligible, approached, consented, assigned to group, completing the programme, completing follow-up, and included in the primary analysis. Reasons for exclusion or loss to follow-up should be reported in broad categories. A second table should show baseline characteristics, including the variables specified in the protocol. The purpose is to show who participated and whether groups were meaningfully comparable, not to conceal imbalances or selectively present favourable characteristics.

The primary outcome table should show the baseline and follow-up scores for the chosen KDQOL-36 scale, the mean or median change within each group, the between-group effect estimate, 95% confidence interval, and p-value. The exact method and sample sizes for each analysis should be shown. Other HRQoL domains may be included as secondary outcomes. The manuscript should state the direction of better scores, explain missing data, and avoid calling a result "significant" without reporting the estimate and its uncertainty.

Functional outcomes should be presented separately from HRQoL scores. For example, if a six-minute walk test is used, the table should report the distance at each time point and the between-group difference in change. Any fatigue measure should be clearly named with its scoring range. If several tests are used, the order and timing of testing should be described in the methods. A functional improvement may help explain a quality-of-life change, but it is not a replacement for the prespecified primary outcome.

Adherence and safety findings should be reported even when the results are unfavourable or uneventful. The report should include the number of sessions prescribed, number completed, attendance distribution, reasons for non-attendance, and protocol modifications. Adverse events should be summarised by type, severity, action taken, and investigator assessment. "No complications occurred" should only be stated when every planned session was monitored and adverse-event reporting was sufficiently complete.

When the actual numbers are added, narrative statements should correspond exactly with tables and figures. The text should not repeat every table cell. Emphasis should be given to the primary outcome, important safety observations, adherence, missingness, and unexpected findings. Results that do not support the hypothesis should be described directly. Selective omission of null findings or presentation of only the most favourable subscale would undermine the credibility of the study.

*Table 2. Suggested table shell for baseline characteristics*

| **Outcome / characteristic** | **Intervention group** | **Usual-care group** |
|---|---|---|
| Number enrolled and analysed | Enter verified n | Enter verified n |
| Age, years | Mean (SD) or median (IQR) | Mean (SD) or median (IQR) |
| Sex / gender, as collected | n (%) | n (%) |
| Duration on haemodialysis | Mean (SD) or median (IQR) | Mean (SD) or median (IQR) |
| Important comorbidities | n (%) | n (%) |
| Baseline primary HRQoL score | Mean (SD) or median (IQR) | Mean (SD) or median (IQR) |
| Follow-up completion | n (%) and reasons for loss | n (%) and reasons for loss |

**13. Discussion:**

The discussion of the completed study should begin with a concise statement of the primary finding and its uncertainty, without claiming a result before analysis. If the programme is associated with greater improvement in HRQoL than usual care, interpretation should consider the size of the between-group difference, the confidence interval, baseline comparability, adherence, and other changes occurring during follow-up. If there is no detectable difference, authors should consider whether the estimate is precise enough to exclude an important benefit or whether the study was underpowered.

A potential explanation for improvement in physical HRQoL is that repeated aerobic and resistance exercise can increase the capacity to perform everyday tasks. (Bernier-Jean et al., 2022) reported that exercise probably improves functional capacity among adults receiving dialysis and may improve the physical component of HRQoL. (Huang et al., 2019) also identified benefits for some physical outcomes. These findings provide a biological and clinical rationale for the intervention, but they cannot be used to infer the local effect in the absence of site-specific results.

It is possible for functional capacity to improve without a statistically detectable change in the overall HRQoL score. Quality-of-life instruments assess a broader range of concerns than exercise capacity, and several domains may be driven by treatment burden, comorbidity, emotional distress, income, and social support. A short intervention may improve a measurable physical task before the patient notices broader changes in daily life. Measurement error, high baseline scores, limited adherence, or insufficient statistical power can also contribute to a null result.

The PEDAL trial by (Greenwood et al., 2021) is useful context for understanding the complexity of exercise delivery during haemodialysis. Implementation, patient acceptability, the dose completed, and outcome selection can shape the apparent effectiveness of an intervention. If the proposed study finds low attendance, the discussion should explore the recorded reasons rather than attributing non-adherence to a lack of motivation. Timings, transport, fatigue, staffing, discomfort, and family responsibilities may all limit participation, and some barriers may be amenable to service redesign.

The KDQOL-36 and other HRQoL instruments should be discussed as patient-reported measures with defined strengths and limitations. (Peipert et al., 2018) evaluated the KDQOL-36 in a large United States dialysis sample, supporting its use as a practical measure while also underlining the need to understand its scales and psychometric properties. Instrument validity does not guarantee

cultural equivalence in every setting. If the local language version has limited validation or questions are difficult to understand, that limitation should be discussed explicitly.

Safety should be interpreted proportionately. A small study with no observed serious adverse events may show that the programme was delivered without obvious safety problems under the study conditions, but it cannot establish that the intervention is universally safe. The number of participants and sessions, completeness of monitoring, and characteristics of enrolled patients determine how much confidence can be placed in the safety observation. Patients with unstable cardiovascular disease or acute illness may have been excluded, limiting generalisability to those groups.

A comparison-group design helps control for changes that might occur over time, but allocation without randomisation remains vulnerable to bias. Intervention participants may be younger, more mobile, more motivated, or more clinically stable at baseline. Statistical adjustment can reduce some measured imbalance but cannot remove all unmeasured differences. The discussion should therefore use language such as “was associated with” rather than “caused” when causal inference is limited. A randomised multicentre study would be a stronger next step if the programme shows feasibility and a promising estimate.

The findings, once available, should be compared with published studies based on similarity of intervention content, duration, dialysis timing, sample characteristics, and outcome instrument. A study using only intradialytic cycling is not directly equivalent to one combining aerobic, resistance, and functional training. A pooled mean change reported by a systematic review may not be expected in a small local sample. Proper comparison explains why estimates may differ instead of assuming that one study has invalidated another.

The discussion should also include patient priorities. A statistically small change could matter to participants if it enables an activity they value, while a larger numerical change in a scale may not be meaningful to every individual. If qualitative feedback is collected, it can help explain acceptability, perceived benefit, and barriers. Such information should be analysed with a defined approach and presented as a complement to the primary outcome, not as proof that a programme works for all patients.

## 14. Clinical implications:

If the programme is feasible and supported by the observed outcomes, the dialysis service could consider a standardised referral pathway for physiotherapy assessment. Screening should be based on functional need and safety rather than age or diagnosis alone. A written exercise plan can help patients, nurses, nephrologists, and physiotherapists share expectations. The programme should remain flexible enough to accommodate fluctuation in symptoms and dialysis-day status, while maintaining consistent documentation of prescribed and completed exercise.

Interdisciplinary coordination is essential. Nephrologists can review medical stability and exercise contraindications; dialysis nurses can monitor the access and treatment; physiotherapists can assess movement, prescribe exercise, and progress the programme; and renal dietitians or mental health professionals can address other contributors to fatigue and reduced well-being. No single clinician can resolve all factors affecting HRQoL. A pathway should make referral routes clear and avoid positioning physical therapy as a replacement for comprehensive kidney care.

Patient education should use straightforward language and locally understandable examples. Advice about physical activity should be consistent with the patient’s fluid restrictions, access care, diet plan, medication schedule, and other clinical instructions. Pictorial sheets may help patients remember exercises, but images should not be interpreted as permission to perform movements without individual assessment. Patients should be encouraged to report symptoms and to adapt the plan when unwell rather than following it rigidly.

Implementation requires staff time, equipment, training, cleaning processes, space, and a process for recording outcomes. Before expanding the programme, a service should review the workload, frequency of missed sessions, patient preferences, equipment maintenance, and safety escalation. A feasible programme should fit the clinical workflow without interfering with dialysis care.

Economic evaluation may be useful in a later study, but cost-effectiveness should not be claimed without collecting the relevant costs and outcomes.

**15. Strengths and limitations of the proposed study:**

A principal strength of the proposed design is its practical focus on an outcome that patients can directly report. Using a validated instrument, a structured exercise manual, standardised safety procedures, and prospective documentation would improve reproducibility. Collecting both HRQoL and functional outcomes can show whether perceived changes are aligned with physical performance. Recording adherence and adverse events also improves the usefulness of findings for a dialysis service considering whether the programme could be implemented routinely.

The likely limitations should be acknowledged before the study begins. A single-centre design may limit generalisability, especially where staffing, language, socioeconomic background, and dialysis practices differ. Non-random allocation can introduce selection bias, and a small sample may provide imprecise estimates. Participants and therapists cannot be blinded to exercise, which may influence expectations or self-reported outcomes. Short follow-up may not show whether changes persist after supervised sessions end (Kumar M, Singh B, Chawla et al., 2026).

The possibility of contamination should be considered if patients in the usual-care group receive exercise advice from staff or share materials with intervention participants. Conversely, differences in attention between groups may influence self-reported scores even when exercise itself has limited effect. Where feasible, HRQoL questionnaires can be administered by an assessor not responsible for delivering the programme, and the data analyst can be provided with group labels concealed until the principal analyses are finalised. These steps reduce but do not eliminate bias.

Measurement limitations can arise if participants complete different language versions, if assessment timing varies widely relative to dialysis, or if a questionnaire is modified without validation. Functional tests can be affected by learning, assessor encouragement, pain, footwear, and daily symptom variation. Missing data may be more common among patients with worse health, making complete-case estimates biased. The protocol should anticipate these problems, and the final report should disclose any deviations rather than presenting the study as more standardised than it was.

A quasi-experimental study can estimate an association and provide useful feasibility information, but it cannot confidently isolate the causal effect of exercise from all other changes. Routine dialysis care, medication changes, intercurrent illness, dietary support, psychological support, and regression to the mean can influence outcomes. A larger randomised controlled study with prespecified stratification and sufficient follow-up may be warranted if the local feasibility data are encouraging. The present protocol should be considered an initial step in a staged programme of evaluation rather than a definitive answer.

**16. Recommendations for future research:**

Future studies should recruit from multiple dialysis centres and include patients with a range of ages, comorbidities, mobility levels, and social circumstances. Multicentre sampling can improve generalisability and support subgroup analyses that are not feasible in a small single-centre study. The intervention should remain adaptable but have a defined core dose so that results can be compared across sites. Publication of the protocol and an intervention manual would help other teams reproduce the programme.

Researchers should agree on a small core set of outcomes: a primary HRQoL measure, a validated functional capacity measure, fatigue, adherence, adverse events, and the dose of exercise received. More consistent measurement could reduce ambiguity across meta-analyses. Where possible, investigators should use a meaningful-change threshold supported by published evidence for the instrument and population. Patient and caregiver involvement can help ensure that chosen outcomes reflect daily priorities rather than only measures convenient for researchers.

Longer-term follow-up is needed to determine whether changes persist, whether participants continue activity independently, and whether a maintenance programme is required. Implementation studies can investigate staffing models, training, digital reminders, home-based

components, and integration into routine dialysis workflows. Economic evaluations should measure intervention costs, healthcare utilisation, and outcomes prospectively. Qualitative research can explore how patients interpret exercise, what makes the programme acceptable, and why individuals may decline or discontinue it.

Future investigations should also study how physical therapy combines with nutrition support, psychological care, sleep interventions, and management of anaemia or pain. These factors may influence both capacity to exercise and the perceived quality of life. Combined interventions must be designed so that the separate components and their delivery can be described clearly. A multidisciplinary approach is likely to be more realistic than assuming that movement alone can resolve every symptom associated with kidney failure.

## 17. Conclusion:

A structured physical therapy programme is a plausible supportive intervention for adults receiving maintenance haemodialysis because reduced physical capacity, fatigue, and participation restrictions are common and clinically important. Existing evidence suggests that exercise can improve functional capacity and may improve the physical component of HRQoL, but effects are not uniform across mental and kidney-specific quality-of-life domains. A programme should therefore use a validated patient-reported outcome, standardised functional testing where feasible, and careful monitoring of adherence and adverse events.

The proposed study at DH Mohali provides a framework for evaluating these questions in a local service. Its value will depend on prospective ethics approval, an adequately justified sample size, a fully described and individualised intervention, consistent outcome assessment, and a prespecified analysis plan. Actual study results must be inserted only after data collection and analysis. Until then, this manuscript is a protocol draft rather than evidence that the programme has improved quality of life at the study site.

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