

Developing an arts-based intervention for patients with end-stage kidney disease whilst receiving haemodialysis

Introduction

Aim: To develop an arts-based intervention for patients with end-stage kidney disease receiving haemodialysis and conduct a feasibility randomised controlled trial.

Objectives:

- Develop an arts-based intervention for patients receiving haemodialysis, informed by a systematic literature review and an interdisciplinary advisory group.
- Identify best practice for implementing an arts-based intervention in a haemodialysis unit.
- Establish recruitment, retention and participation rates for a randomised controlled trial.
- Identify time needed for recruitment, data collection and data analysis.
- Explore the acceptability of an arts-based intervention for patients and staff on a haemodialysis unit.
- Explore the suitability of outcome measures.
- Identify estimated costs of delivering the arts-based intervention and methods for assessing cost-effectiveness in a full trial.
- Develop the protocol for a definitive randomised controlled trial and economic evaluation of an arts-based intervention compared to usual care.

Background

End-stage kidney disease (ESKD) is the final stage of chronic kidney disease and is defined by an estimated glomerular filtration rate (eGFR) of <15 ml/min/1.73m² (National Institute for Health and Care Excellence, 2014). The eGFR is the estimated rate of fluid filtration within the glomerulus of the kidney and is the main indicator of renal function. Patients with ESKD are poly-symptomatic and experience difficult symptoms including fatigue, pruritus, pain, nausea, sexual dysfunction and muscle weakness, which can profoundly impact quality of life (QoL) (Raj *et al.*, 2017). ESKD is treated with renal replacement therapies (RRT), such as haemodialysis. Haemodialysis is a difficult and time consuming treatment that requires patients to attend hospital up to three times a week for up to four hours each time. During treatment the patient is connected to a dialysing unit that filters their blood and removes waste products and excess fluid; replacing the role of the kidneys. Patients receiving haemodialysis have lower health-related quality of life (HRQoL) than the general population (Lowney *et al.*, 2015). Lower HRQoL is associated with increased morbidity and mortality in patients on haemodialysis (Liebman *et al.*, 2016). Patients receiving

haemodialysis also have higher rates of anxiety and depression than the general population or patients with ESKD who receive a renal transplant (Cohen *et al.*, 2007; Nabolsi *et al.*, 2015; Chen *et al.*, 2016; Kokoszka *et al.*, 2016).

Depression is an independent predictor of mortality in haemodialysis populations (Chilcot *et al.*, 2011; Barros *et al.*, 2016); this may result from poor treatment adherence (Ossareh *et al.*, 2014; Nabolsi *et al.*, 2015), maladaptive health behaviours (Ziegelstein *et al.*, 2000), self-harm and increased suicide risk (Pompili *et al.*, 2013). Treatment for ESKD involves an extensive treatment regimen which includes adherence to dialysis sessions, medications, fluid restriction and a restrictive diet (Nabolsi *et al.*, 2015). Non-adherence to this regimen can result in increased mortality risk – missing a single dialysis session each month increases the risk of death by 30% (Denhaerynck *et al.*, 2007). Depression is a contributing factor to non-adherence for patients receiving maintenance haemodialysis (Ossareh *et al.*, 2014). Patients with depression are also less likely to follow guidance on healthy lifestyle behaviours in general, including recommendations on diet, exercise and stress reduction (Ziegelstein *et al.*, 2000). Fewer studies have explored the impact of anxiety alone on mortality and morbidity, with the majority of research considering depression and anxiety in combination (Preljevic *et al.*, 2013). A prospective cohort study of 100 patients with ESKD in Holland found that symptoms of anxiety, as measured by the Beck's Anxiety Inventory (Beck *et al.*, 1988), had a statistically significant relationship with poorer clinical outcomes in chronic kidney disease patients who were not on dialysis (Loosman *et al.*, 2015). Therefore symptoms of anxiety and depression have the potential to impact physical wellbeing of patients receiving haemodialysis.

A strong relationship exists between HRQoL, anxiety and depression in patients receiving haemodialysis. A cross-sectional multi-centre study conducted by Bujang *et al.*, (2015) in Malaysia sampled 1332 patients receiving haemodialysis or peritoneal dialysis and found depression, anxiety and stress correlated significantly with the WHOQOL-BREF, a brief questionnaire measuring HRQoL. This relationship was also found in a cross-sectional study conducted in Greece, where depression and anxiety were associated with HRQoL scores in patients on haemodialysis, after adjusting for confounding variables (Vasilopoulou *et al.*, 2015). Cohort studies within the United Kingdom and Ireland also report this association, where depression scores of patients receiving haemodialysis have been found to significantly correlate with the EQ-5D-5L, another valid HRQoL measure (Lowney *et al.*, 2015). A systematic literature review by García-Llana *et al.*, (2014) reviewed 38 articles exploring the

relationship between depression, anxiety, stress and HRQoL in relation to treatment adherence in patients receiving haemodialysis. Each of the identified articles found a statistically significant relationship between anxiety, depression and HRQoL. There are a number of different factors that contribute to this established relationship. Depression can influence QoL in a number of ways, including impacting mood and motivation (McCann *et al.*, 2000; Farragher *et al.*, 2017). As previously mentioned depression can lead to poor treatment adherence in patients receiving haemodialysis (Nabolsi *et al.*, 2015), which increases symptom burden. Symptoms of ESKD can impact mood and increase depressive symptoms (Cao *et al.*, 2017; Maung *et al.*, 2017; Wan Zukiman *et al.*, 2017). A review by Farragher, *et al* (2017) found the relationship between fatigue and depression so robust that they recommend routine screening for depression in patients receiving haemodialysis who present with fatigue. The relationship between HRQoL, anxiety and depression is enmeshed, yet depression and anxiety remains underdiagnosed and under-treated in patients receiving haemodialysis (Watnick *et al.*, 2003; Cohen *et al.*, 2007; Cukor *et al.*, 2008; Kokoszka *et al.*, 2016).

One reason for this complex dynamic is the overlap between anxiety, depressive symptoms and the uremic state; many symptoms of depression and anxiety, such as fatigue, anorexia, sleep disturbances, appetite disturbances and sexual dysfunction are identical to symptoms of uraemia, rendering it be difficult to differentiate anxiety, depression from the clinical picture of ESKD (Cohen *et al.*, 2007; Cohen *et al.*, 2016). Stigma surrounding depression also contributes to the rates of diagnosis and treatment. Wuerth *et al.*, (2008) screened 380 patients receiving haemodialysis or peritoneal dialysis using the Beck Depression Inventory (BDI) to identify who may be experiencing a depressive disorder. While 49% were identified to be at risk, 55% of those identified declined a mental health assessment. Some patients regarded this assessment as a sign of weakness, and were apprehensive of being stigmatised if they acknowledged symptoms of depression. Therefore HRQoL, anxiety and depression cannot be considered in isolation from each other when caring for patients with ESKD. This strong relationship results in a need for creative, holistic approaches to address these issues, in a way that is cognisant of the multiple contributing factors.

The application of arts in health has received recent interest because of its potential to improve patient outcomes and reduce costs for the National Health Service (NHS) (All-Party Parliamentary Group on Arts Health and Wellbeing, 2017a). Arts-based interventions involve the implementation of arts activities in a healthcare context to deliver a creative experience

(Centre for Arts in Medicine, 2017). They have been shown to improve QoL, symptom burden and mental health (Staricoff and Clift, 2011; Bungay *et al.*, 2014; Sonke *et al.*, 2015) in a variety of settings, including medical-surgical units (Sonke *et al.*, 2015), primary care (Crone *et al.*, 2012) and cancer care (Kim *et al.*, 2017), but there is a lack of research exploring their effect in renal populations. Emphasis across healthcare research remains on arts therapies which are a form of clinical intervention, administered by a professional therapist within a psychotherapeutic framework, to meet clinical objectives (Health & Care Professions Council, 2009), although even in this area, few studies have been published involving patients receiving haemodialysis. Less attention has been given to participatory arts-based interventions by funding bodies such as the National Institute of Health Research. As a result, research examining arts-based interventions tends to be small in scale (All-Party Parliamentary Group on Arts Health and Wellbeing, 2017b), lack longitudinal follow-up (Boyce *et al.*, 2017) and often focus on receptive interventions such as music listening which are easier to implement than more complex arts in health programmes or artistic mediums (Staricoff and Clift, 2011; Bungay *et al.*, 2014). There is also a lack of research examining the effect of arts-based interventions in patients with ESKD. While a systematic literature review by Kim *et al.* (2015) identified a number of randomised controlled trials using music-listening interventions, other forms of arts-based interventions have not been explored using this methodology.

In order to establish the effectiveness of arts-based interventions rigorous randomised controlled trials are the most robust method of evaluation. However there are difficulties associated with randomised controlled trials, particularly around recruitment and retention of participants (Donovan *et al.*, 2014). This is exacerbated in palliative care trials where participation rates under 50% are common (Hanson *et al.*, 2015). Trials in nephrology, the most under-researched field of internal medicine, also experience problems retaining participants (Palmer *et al.*, 2011). The reasons for these low recruitment and retention rates are multi-factorial, including ethical implications of working with patients who have an end-stage illness, the emotional distress and burden placed on participants who may experience severe symptoms such as fatigue, pain and nausea (Hanson *et al.*, 2015).

Methodology in arts-based intervention research needs to be considered due to the lack of randomised controlled trials conducted using non-music art forms as an intervention (Bungay *et al.*, 2014; Boyce *et al.*, 2017). Music-listening is a straightforward intervention that typically involves patients listening to personal Mp3 players through headphones

(Momennasab *et al.*, 2018). It is difficult to apply research methods used in music-listening interventions to more dynamic arts-based interventions that require facilitation and mediums which may impact on the clinical environment (Sonke, 2017). These more dynamic arts-based interventions meet the Medical Research Council's description of a complex intervention (Medical Research Council, 2009), in that it involves several interacting components that can impact on implementation, evaluation and the context in which it is delivered. There is a tendency of complex interventions to fail to show a significant effect in randomised controlled trials (Levati *et al.*, 2016). This absence of detectable effect may not result from an ineffective intervention, but instead could be a consequence of the logistical difficulties in standardising and evaluating complex health interventions in an experimental process (Medical Research Council, 2009). Consideration needs to be given to optimising the intervention and the trial process, such as recruitment procedures and randomisation, for the context in which the intervention will be delivered. To address these issues Levati *et al.* (2016) recommend feasibility studies. These focus on real world implementation during the development of the intervention and research design, by involving key stakeholders throughout each stage of the process and 'in vivo' exploration of problems that occur with implementation and trial processes during feasibility testing.

When exploring the staff perceptions of arts-based interventions, the focus in the literature is on how the intervention impacts the patients, with fewer studies examining the effect of the intervention on healthcare staff themselves (Bungay *et al.*, 2014; Boyce *et al.*, 2017). It is particularly important to consider the potential positive and negative effects of arts-based interventions on healthcare staff, due to the unique nature of the clinical working environment. A critical review by Wilson *et al.*, (2015) explored healthcare staff perceptions of arts-based interventions and identified numerous benefits of arts-based interventions including reductions in stress and improved working relationships. However the potential negative outcomes included interference with work flow, increased stress and restricted communication between healthcare staff. Any negative impact on the ability of healthcare staff to perform their job could have significant consequences for patient safety; therefore the acceptability of an intervention for healthcare staff is important to consider (May, 2013). The acceptability for patients must also be taken into consideration. If an effective intervention is burdensome or non-engaging, patients will not participate and not experience the benefits (May, 2013). In order to evaluate whether an intervention is acceptable in practice, a process evaluation must be conducted. Process evaluations provide a detailed understanding of

complex interventions by examining their implementation, mechanism of impact and context (Moore *et al.*, 2015).

As already described, the All Party Parliamentary Group report on the Arts for Health and Wellbeing (All-Party Parliamentary Group on Arts Health and Wellbeing, 2017b) claimed that arts-based interventions have the potential to reduce costs within the NHS, however the only cost-effectiveness analysis cited within this comprehensive report was for a single to a community singing intervention for healthy older people (Skingley *et al.*, 2011). The estimated savings within the report were predominantly based on the costs associated with disease and the assumption that the interventions are effective; this is not a rigorous method of economic evaluation. Markov models are needed to make long-term projections about the economic implications of an intervention. These models require disease progression rates and cost data obtained from economic evaluations within large-scale randomised controlled trials (Komorowski and Raffa, 2016). The Arts for Health and Wellbeing report reflects the lack of cost-effectiveness analysis and economic evaluations conducted for arts-based interventions (Craemer, 2009). Cost-effectiveness analyses are important as they are the basis of decision making for health intervention recommendations by NICE (Ogden, 2017). In order to ensure that the effectiveness of an intervention can guide healthcare policy, economic evaluations and cost-effectiveness analysis are needed to establish justification for funding. However, due to the total absence of economic evaluations for arts-based interventions implemented within hospital settings, it is important to explore the best methods for conducting such cost-effectiveness analyses.

As there are identified barriers to recruitment and retention of participations in palliative care and nephrology research, arts-based interventions are complex and under-researched, and no formal cost-effectiveness analyses have been conducted a feasibility trial, process evaluation, and feasibility economic evaluation are necessary to inform optimal strategies and methods for a definitive randomised controlled trial (Bowen *et al.*, 2009)

Research design

The study will consist of four phases and will utilise a mixed-method design. Phase 1 will consist of the development of the intervention, phase 2 will involve a quantitative feasibility randomised controlled trial, phase 3 will involve a qualitative process evaluation and phase 4 will involve feasibility testing for an economic evaluation.

The RE-AIM mixed methods framework (Forman et al., 2017) will be used to guide the research process. The framework outlines the core aspects of a complex intervention that should be explored to enhance the generalisability of findings (Glasgow and Estabrooks, 2018). The core aspects include the intervention's reach, effectiveness, adoption, implementation and maintenance. Not all RE-AIM objectives can be met within a feasibility study, for example, the maintenance of the intervention over time. However the framework will be used to inform research questions, data collection and outcomes appropriate for a feasibility study.

Plan of Investigation

Research Setting

The research will be conducted in the haemodialysis unit at Antrim Area Hospital in the Northern Health and Social Care Trust, Antrim, Northern Ireland.

Phase 1 – Development of the intervention

The development of the intervention will follow the comprehensive framework provided by Fancourt in 'Arts in Health' (2017). This framework provides an overview of seven steps following a problem-based solution approach for developing and evaluating arts-based interventions for use in healthcare. The steps include mapping the environment, gaining concrete experience, conducting reflective observation, undertaking abstract conceptualisation, active experimentation, reviewing and reconnecting.

The intervention will be developed in conjunction with the inter-disciplinary Advisory Group for the research project. The Advisory Group will include healthcare staff representatives from the haemodialysis unit at Antrim Area Hospital, two artist representatives from Arts Care Northern Ireland, the CEO of Arts Care Northern Ireland, three patient representative from the Northern Ireland Kidney Patient Association, members of the Renal Arts Group at Queen's University Belfast, a representative from University of Florida school of Arts in Medicine, the manager of Community Wellbeing in the Northern Trust and a statistician. This group will meet approximately every 3 months, both face to face and virtually, in order to provide guidance on the research project and the development of the intervention.

The Template for Intervention Description and Replication (TIDieR) checklist will provide an overview of the specific components to be considered when describing the intervention in any future publication (Hoffmann *et al.*, 2014).

The development framework outlines the need to identify the existing evidence base (Fancourt, 2017), therefore a systematic literature review will be conducted. Searches will be undertaken in the following databases: MEDLINE, Embase, PsycINFO, CINAHL, Scopus, and Web of Science. Grey literature will be searched, including reports published by arts in health agencies and online theses databases. The literature review will aim to address specific research questions:

1. What arts-based interventions have been used to support patients with ESKD?
2. How have arts-based interventions been implemented in clinical settings?
3. How have arts-based interventions impacted on patients with ESKD?
4. What methods have been used to evaluate outcomes?
5. What are the costs associated with implementing arts-based interventions in a clinical setting?

The methodological standard of identified articles will be critically appraised using the Joanna Briggs Institute (JBI) critical appraisal checklists (The Joanna Briggs Institute, 2017). These were selected as they cover a wider variety of methodological approaches compared to other critical appraisal tools, such as Critical Appraisal Skills Programme (CASP) tools (CASP UK, 2017).

Phase 2 – Feasibility Randomised Controlled Trial

Participants

Participants will include patients receiving haemodialysis in the outpatient haemodialysis unit at Antrim Area Hospital.

Eligibility criteria for patients:

- Age 18 or over
- Able and willing to participate
- Receiving haemodialysis

There is little consensus on the appropriate sample size for a feasibility study, with guidance ranging from 12 per arm (Julious, 2005) to 50 per arm (Sim and Lewis, 2012). A formal sample size calculation is not appropriate for feasibility studies as the objectives do not include establishing the effectiveness of an intervention. Feasibility studies should instead focus on the acceptability of trial processes or an intervention, including the willingness of participants to be randomised, the time needed to collect and analyse data and response rates to outcome measures (Eldridge *et al.*, 2016). This inconsistency in sample size guidance could reflect the inconsistency in how pilot and feasibility studies are reported. A review of 54 pilot and feasibility studies by Arain *et al.* (2010) concluded that pilot/feasibility studies were poorly reported and placed an inappropriate emphasis on hypothesis testing, with 81% of studies conducting hypothesis testing and a further 35% using a sample size calculation to ensure adequate statistical power for this purpose. Recent reviews of pilot studies confirm that inappropriate hypothesis testing is a common issue (Kannan and Gowri, 2015). The report of statistically significant results tends to be opportunistic, in that the study may not have been initially designed to establish effectiveness but because a statistically significant result was found it was reported, which decreases the likelihood of a follow up definitive RCT. This calls into question the validity of the effect, as the study was not designed for the purpose of hypothesis testing, and therefore would not have the rigour of a definitive RCT (Eldridge *et al.*, 2016).

The justification for larger sample sizes in feasibility studies is to obtain narrow standard deviations on outcome measures to maximise precision in a future power calculation (Sim and Lewis, 2012; Teare *et al.*, 2014). However there is disagreement over whether this is an appropriate method to inform power calculations, or whether it's an appropriate objective at the feasibility and piloting stage, as to obtain a narrow standard error for a precise power calculation the sample within the feasibility study would need to approach the size of a fully powered randomised controlled trial (Kraemer *et al.*, 2006). This would in turn increase the likelihood of identifying a statistically significant effect during the feasibility stage, which can be inappropriately reported, and reduce the likelihood of a follow up RCT (Lancaster *et al.*, 2004) . A sample size of 30 is recommended by the NIHR's Research Design Service for the estimation of a parameter, such as sample size, recruitment or attrition rate, for a definitive randomised controlled trial, although they recognise that advice varies from 24 to 50 participants. Due to the increased risk of identifying a statistically significant result with larger sample sizes, and practical limitations of a small, single centre study, a sample size of

30 was selected for the feasibility RCT. A university statistician was consulted who confirmed that a sample of 30 was an appropriate sample size to meet the objectives of the study.

Recruitment

Eligible patients will be approached by a gatekeeper working on the haemodialysis unit. Posters will also be displayed in the waiting area of the haemodialysis unit. These posters will draw attention to the research taking place and will instruct the patient to speak to a member of their healthcare team, who will act as a gatekeeper, for more information on the study if they are interested in participation. The gatekeeper will be provided with an initial approach script that will contain an overview of the study and important information about trial processes. The script will also outline how to respond if a patient expresses an interest in participating, or if they decline to take part. Screening logs will be used to measure the proportion of patients who are eligible and who are interested in the research. Patients who express interest and agree for their name to be passed on will receive an information sheet from the gatekeeper (Appendix 1), which will contain the contact details of the researcher. The gatekeeper will seek permission from the patient to pass their name on to the researcher. The patient will be provided a period of at least 48 hours to decide if they wish to participate, before the researcher will approach them with a consent form and provide the patient an opportunity to ask any further questions (Appendix 2).

Randomisation

The proportion of eligible participants willing to be randomised will be collected through the use of screening logs (Lancaster *et al.*, 2004). Participants will be randomly allocated to a control group or experimental group following the collection of baseline data. Block randomisation at a ratio of 1:1 will be used to ensure both groups comprise the same number of participants (Suresh, 2011). Patients will be randomly allocated according to the days of the week they attend the unit for haemodialysis, as opposed to at an individual level. As the renal unit is an open environment allocation according to shift pattern will reduce the risk of participants within the control group viewing implementation of the intervention, which would introduce potential contamination (Mc Daid *et al.*, 2006). Sealed envelopes will contain the allocation and these will be stored in a locked filing cabinet on site, and will be opened once consent and baseline data have been obtained. Participants who are randomly allocated to the control group will be instructed not to participate in any art activities during

their haemodialysis sessions throughout the study, but that once data collection is completed they will be provided with art supplies and participate in a facilitated session.

Data Collection and Management

Feasibility measures

The main feasibility outcome of interest will be the recruitment, participation and retention rate of participants. Assessing the ability to recruit and retain participants is a common issue explored in feasibility trials (Lancaster *et al.*, 2004; Bugge *et al.*, 2013; Arain *et al.*, 2016; Avery *et al.*, 2017). As barriers to recruitment exist in palliative care research (Hanson *et al.*, 2015), and nephrology research commonly experiences high attrition rates (Palmer *et al.*, 2011), it is important to establish the feasibility of recruiting and retaining the participants needed for a definitive randomised controlled trial. Baseline demographic and clinical data will include age, gender, ethnicity, socio-economic status, education, kidney diagnosis, dialysis vintage, number of co-morbidities and frailty as measured by the Clinical Frailty Scale; these will be collected to explore factors that may influence participation in a full trial.

Clinical outcome measures

Arts-based interventions can improve depression, a common issue in patients receiving haemodialysis (Bujang *et al.*, 2015). Improvements in depression have been reported in receptive arts groups; in a study by (Dowrick *et al.*, 2012) depression scores were measured in patients clinically diagnosed with depressive disorders using the PHQ-9, and a statistically significant reduction in depression was found after engagement in a reading group. Arts-based interventions have also been shown to impact anxiety, another common issue amongst patients receiving haemodialysis (Cohen *et al.*, 2016). As discussed earlier depression and anxiety are highly prevalent and under-addressed amongst patients with ESKD receiving haemodialysis, therefore depression and anxiety will be measured as a clinical outcome. These will be collected through the use of the Hospital Anxiety and Depression Scale (HADS), which has been validated in patients with ESKD (Loosman *et al.*, 2010). The scale measures depression and anxiety within the same tool, allowing independent exploration of two outcomes with a subscale analysis (Annunziata *et al.*, 2011).

Arts-based activities have also been found to contribute to QoL in clinical populations (Staricoff and Clift, 2011; Sturm *et al.*, 2014; Boyce *et al.*, 2017). As previously discussed patients receiving haemodialysis have lower HRQoL than the general population, and a

variety of factors contribute to this outcome. These include not only the physical symptoms patients experience, but psychological and social consequences of the disease and the associated treatments (Kang *et al.*, 2015). The Kidney Disease Quality of Life (KDQoL-36) is a commonly used measure of HRQoL in renal literature, is valid and reliable, and has been identified as providing the most comprehensive overview of factors that contribute to QoL (Glover *et al.*, 2011). Therefore the KDQoL-36 will be used to measure QoL.

The clinical outcome measures will be collected at baseline and immediately after the intervention. A pre/post-test design is common in arts-based intervention research and allows researchers to evaluate improvements in health outcomes over a short time period (Bungay *et al.*, 2014; Kim *et al.*, 2017). However, arts-based intervention research has faced criticism due to lack of longitudinal follow up, which would be necessary to identify whether arts-based interventions are sustainable in a clinical setting, and whether the benefits are lasting (Boyce *et al.*, 2017). Participants who are lost to follow up in longitudinal RCTs concerning complex healthcare interventions tend to be older, diagnosed with a chronic illness and have higher co-morbidity (Peterson *et al.*, 2012), common demographic factors in patients with ESKD (Zyoud *et al.*, 2016). To establish the feasibility of follow up within a definitive randomised controlled trial and establish attrition rates over time, a longitudinal follow up will also occur. This period will be limited by the time frame of the PhD programme, and clinical outcome measures will be collected pre and post intervention and at 6 weeks and 3 months after the intervention commences.

Data analysis

Data analysis will be conducted using the Statistical Package for the Social Sciences (SPSS v 24). Descriptive statistics will be used to present baseline demographic and clinical data. Categorical data will be presented as frequencies and percentages, while continuous data will be presented as means and standard deviations. Recruitment, participation and retention rates will be reported and presented in a CONSORT flow diagram (Eldridge *et al.*, 2016). The proportion of patients who were eligible for recruitment, who consented to participation and who completed the study will be calculated and presented with 95% confidence intervals. Exploratory inferential statistics will be conducted, but no conclusions on the effectiveness of the intervention will be made from the results. Independent t-tests (or the non-parametric equivalent Mann-Whitney U) will be conducted to compare the scores of the experimental group and control group. The majority of arts-based intervention research involves pre-and-

post-test designs; therefore a repeated measures t-test (or the non-parametric equivalent Wilcoxon Matched Pairs test) will also be conducted to compare the mean scores of the experimental before and after receiving the intervention. An analysis of variance will be conducted to explore any potential sub-group analysis that may be relevant within a future RCT.

Phase 3 – Process evaluation

Participants

Participants will include both patients who have been recruited into phase 2 of the study, and healthcare staff working on the unit during the implementation of the intervention. Healthcare staff from the unit will also be recruited into the process evaluation.

Eligibility criteria for healthcare staff:

- A member of the multidisciplinary team, including nurses, healthcare support workers, doctors, dietitians, social workers and counsellors.
- Have had experience with the intervention.
- Have worked in a clinical renal setting for more than 3 months

Familiarity with the context of the clinical environment is needed to inform the acceptability of the intervention (May, 2013). Context includes the social system within in the work place, taking into consideration social norms, material resources, and collective commitment (May, 2013). A qualitative study by Farnell and Dawson (2006) interviewed critical care nurses over 6 months after transferring from general medical wards. Up to 3 months after commencing their new post nurses continued to report experiences relating to their socialisation, including the setting feeling ‘so different’, feeling deskilled in the new environment and being unable to meet the high expectations they set for themselves. At 6 months follow up these experiences were no longer reported. New staff and students require time to familiarise themselves with the clinical environment, the expectations involved in their role and the social structure of the unit (Valdez, 2008). Therefore healthcare staff who have worked in a renal setting for less than 3 months and students on placement during the intervention will be excluded from the evaluation.

Recruitment

During data collection for phase 2 patients will be offered with the opportunity to participate in the process evaluation. A separate information sheet (Appendix 3) will be provided to interested participants by the researcher, participants will be given a minimum of 48 hours (time between dialysis sessions) to consider participation and a consent form (Appendix 4) will be provided for completion at the start of each interview.

Healthcare staff will be recruited for the process evaluation by purposive sampling. During the feasibility trial the ward manager, who will act as a gatekeeper, will approach healthcare staff and provide them with a participant information sheet containing contact details for the researcher (Appendix 5). Due to managerial and social hierarchies within hospitals healthcare, staff may feel pressure to participate; therefore the staff will be asked to contact the researcher if interested, so the gatekeeper will not be aware of who is participating.

Data Collection and Management

Approximately 13 patients will be recruited into the process evaluation. Simulations have shown that this sample size of 10 should identify 80% of problems within a complex intervention (O’Cathain *et al.*, 2014), while data saturation is likely to be reached at 12 interviews on average (Guest *et al.*, 2006). The principle of 10 + 3 for data saturation outlines that a minimum of 10 interviews should be conducted, followed by at least 3 consecutive interviews that present no new findings (Francis *et al.*, 2010), therefore a sample of 13 patients will be recruited for semi-structured interviews. Approximately 5 healthcare staff will be recruited into each focus group, with a proposed total of 3 focus groups (Schneider *et al.*, 2009). The dialysis unit in which the study is taking place is relatively small, therefore the focus groups will be limited by the amount of staff available who meet the eligibility criteria and the requirement to produce a manageable amount of data for the time limitations of the study (Carlsen and Glenton, 2011; O’Cathain *et al.*, 2014). However, these are approximate sample sizes, and data collection will continue until data saturation is reached. The researcher will provide the participants with a consent form prior to commencement of the focus group (Appendix 6). Data saturation will be determined when there is no new data being found from which additional themes can be developed (Guest *et al.*, 2006).

Data collection for the process evaluation will occur in parallel to the feasibility randomised controlled trial, during implementation of the intervention and follow up (Moore *et al.*, 2014). The semi-structured interviews will be conducted with patients in their own home to maintain

confidentiality and avoid the power dynamic present in a clinical setting (Green and Thorogood, 2004). This approach will be flexible and patients can request that interviews occur during the haemodialysis session or on the unit if this is their preferred location. The focus groups with staff will take place in a private room on the haemodialysis unit. The process evaluation will follow the MRC guidance on process evaluations for complex evaluations (Moore *et al.*, 2014). It will therefore focus on the acceptability of the intervention, barriers and facilitators to implementation, the appropriateness of outcome measures, motivations for participation, reasons for continued engagement and potential mechanism of impact of the intervention.

The semi-structured interviews and focus groups will use interview guides consisting of open questions informed by the RE-AIM QuEST framework (Forman *et al.*, 2017). The interview guide will be flexible to ensure that participants can express and explore perspectives that they consider relevant to implementation, and will be reviewed by the advisory group and supervisory team who are responsible for providing objective oversight.

Data Analysis

The semi-structured interviews and focus groups will be recorded and transcribed verbatim. Inductive thematic analysis will be used to analyse the data collected. Thematic analysis involves identifying and coding central themes within qualitative data through an iterative process (Braun and Clarke, 2006). Themes are conceptualised as ideas that reflect some level of meaning within the data (Jugder, 2016). The first step will involve descriptive coding of the data line by line, identifying words or phrases that capture salient components in the data. During the second step, interpretive codes will be synthesized from the descriptive codes. The interpretive codes will then be arranged into hierarchical categories, forming final overarching themes. (Tracy, 2013). The purpose of a process evaluation is to develop an understanding of the intervention, trial, context and mechanisms of change, therefore data analysis must be focused on answering these research questions (Grant *et al.*, 2013). Themes will be identified at a semantic level, in that they will develop from the explicit content contained within the data. This is different to identifying themes at a latent level, which requires a more hermeneutic approach (Braun and Clarke, 2006). Semantic themes are appropriate for a process evaluation as the aim is to gather explicit information on the implementation of an intervention and trial processes (Forman *et al.*, 2017).

Investigator triangulation will be used to ensure validity of the identified themes. This will involve regular review of the analysis and themes by the supervisory team to ensure that subjective bias is controlled for during the analysis of the data (Steinke, 2004). Method triangulation will also be used by comparing the quantitative data collected during phase two and comparing semi-structured interviews, focus groups and field notes (for example, comparing demographic or clinical data and recruitment rates with themes related to participation). Data source triangulation will also be used in the process evaluation. This involves collecting data from a variety of sources, and will be achieved by collecting information from a wide variety of participants, including participants from phase two, participants who declined to take part in the trial, and healthcare staff working on the unit (Carter *et al.*, 2014). The importance of objective oversight has been highlighted in the MRC guidance on process evaluations, due to potential bias that researchers involved in the development of an intervention may bring when evaluating its acceptability (Moore *et al.*, 2015).

Phase 4 – Economic evaluation

Data collection and management

Feasibility studies do not have the sample size required for the statistical power needed to establish effectiveness, therefore conducting a full cost-effectiveness evaluation within a feasibility study is not recommended (Hounscome and Shearer, 2015). However the feasibility of data collection methods and the appropriateness of outcome measures can be evaluated during a feasibility study to inform a full economic evaluation within a definitive randomised controlled trial.

Health and social care costs of participants will be collected using Patient Service Use Logs previously used in the Palliative Care in Chronic Kidney Disease study (PACKS) (Agus *et al.* (2017). These logs will collect information on health and social care service use during the intervention. The logs will be collected post-intervention and at six weeks and three months follow up. The outcome of interest will be the feasibility of using a Patient Service Use Log in a full economic evaluation according to proportion of participants who complete the Patient Service Use Log.

The EQ-5D-5L will be administered to patients in conjunction with the clinical outcome measures, pre/post-intervention and at 6 weeks and 3 months follow up. The EQ-5D-5L is recommended by NICE for deriving utility values for the calculation of quality adjusted life years in cost-effectiveness analysis within definitive economic evaluations (National Institute for Health and Care Excellence, 2012) and has been shown to be a valid measurement of health status in patients with ESKD (Cleemput *et al.*, 2004). However it is important to consider the burden of questionnaires on participants during a randomised controlled trial. The acceptability of administering the EQ-5D-5L to patients in conjunction with the KDQoL-SF 36 and the HADS will be explored by examining the completion rates and proportion of missing data for the EQ-5D-5L.

Data analysis

A cost-consequence analysis is recommended by the National Institute of Health Research for both complex interventions and feasibility studies where the outcomes of interest are not clear (Hunter and Shearer, 2014). Costs and outcome measure data for both the intervention and control group will be presented using means and 95% confidence intervals in order to show a general overview of the economic costs of the intervention, and differences in resource use and outcome measures between groups. Completion rates and missing data for the Patient Service Use Log and the EQ-5D-5L will be presented as frequencies to assess the feasibility of data collection.

Progression Criteria

Progression to a definitive RCT will be determined by recruitment rates and the acceptability of the intervention for patients and staff.

- 75-100% of the target sample size recruited will result in progression to a definitive RCT.
- 50-74% of the target sample size recruited will result in progression to a definitive trial after reviewing the protocol and data from the process evaluation, and making appropriate amendments to address barriers to recruitment.
- 25-49% of the target sample size recruited will result in progression to a definitive trial after reviewing the protocol with input from potential co-applicants to ensure that the protocol is modified to enhance recruitment rates.

- Less than 25% of the target sample size recruited will probably result in the trial not progressing, unless a significant modifiable barrier is identified within the process evaluation.
- Progression to a full trial will be contingent on the acceptability of the intervention for both patients and staff regardless of recruitment rates. This will be assessed within the qualitative process evaluation (Forman *et al.*, 2017). Any necessary modifications identified within the process evaluation to improve the intervention will be made prior to progression to a definitive trial.

The progression criteria for recruitment are the criteria used by the Northern Ireland Clinical Trials Unit (McConnell *et al.*, 2016), and were confirmed by contacting Professor Mike Clark via e-mail. The inclusion of a qualitative component within progression criteria is recommended by O’Cathain *et al.*, (2014) as qualitative research may be able to identify potential harms of an intervention that would not be captured within the quantitative results.

Ethical Considerations

As the chief investigator is an academic of Queen’s University Belfast, the University will sponsor this research and will be responsible for independent peer review of the study protocol. This research falls under Category B research in the University regulations for research involving human participants from within a healthcare trust (Queen’s University Belfast, 2013), therefore the application for ethical approval will be made to the Office of Research Ethics Committees Northern Ireland (ORECNI), through the Integrated Research Application System (IRAS). The local collaborator on site will be the consultant nephrologist Dr Robert Mullan.

Informed Consent

To ensure informed consent is obtained freely from participants they will initially be approached by the gatekeeper on site, who will provide them with a verbal summary of the project and the participant information sheet. This will ensure that participants feel free to decline to participate by removing the power dynamic that may be present in a direct approach from the researcher. The participant information sheet (Appendix 1, Appendix 3, Appendix 5) will contain information on the purpose and process of the research, how data will be collected, stored, and used, their ability to withdraw from the study at any time, the

right to refuse to answer questions during the interviews, a guarantee of anonymity and how this will be maintained, the expectations of participants, including time commitments and any potential risks or difficulties that could arise during the research (Connolly, 2003). Contact details for the researcher will be provided should the participant have any questions. The patient will be given time to consider participation over 48 hours, before finally being approached by the researcher with a formal consent form.

Confidentiality and Anonymity

Participants will be allocated codes for the purpose of data collection for the feasibility randomised controlled trial. All data will be stored in accordance with the Data Protection Act (2018). All identifiable information will be confidential and stored in a locked filing cabinet in a locked room at Queen's University Belfast School of Nursing and Midwifery. For the process evaluation pseudonyms will be allocated to participants during transcription (Allmark *et al.*, 2009). Data will be stored for a minimum of 5 years and subsequently destroyed. The data recorded on all audio recording devices will be erased once it has been transcribed and stored on a secure, encrypted computer. As focus groups will be used for data collection during the process evaluation, the importance of confidentiality will be reiterated prior to the commencement of each group. During the process evaluation, participants will be provided with limitations of confidentiality and anonymity on information sheets prior to commencement of the study. Participants will be informed that if the interview or focus group provides evidence for serious concerns regarding child welfare, the safety of the participant or the safety of others, that a third party will have to be informed.

Welfare of Participants

The research involves participants who have an advanced illness. During the feasibility randomised controlled trial participants will be receiving an arts-based intervention whilst also receiving haemodialysis. Due to the importance of maintaining vascular access and not inhibiting the work of healthcare professionals, the intervention will be designed with input from healthcare professionals working in this clinical setting, as well as artists from Arts Care Northern Ireland who have experience adapting arts-based interventions to the clinical environment. The process evaluation will also occur in parallel to the implementation of the intervention, ensuring that any issues with the intervention are identified and can be addressed during the trial (Moore *et al.*, 2014).

As the questionnaires participants fill out explore subjects such as quality of life and mental health, and the interviews and focus groups may broach sensitive subjects relating to the experiences of living with ESKD or the experiences of working with patients who have an end-stage illness, there is a potential for participants to experience emotional distress. A distress protocol (Appendix 7, Appendix 8) will be in place to address these issues (Haigh and Witham, 2015) and participants will be provided with information regarding relevant supportive services available. Participants will be reminded they can stop the interview at any time, they are not obligated to answer questions they feel are too sensitive, or provide information they are not comfortable sharing. A renal counsellor will also be present on the advisory group and will provide guidance on maintaining the emotional wellbeing of participants. Two additional distress protocols have also been developed for the potential that a participant discloses suicidal thoughts (Appendix 9) or achieves a score on the Hospital Anxiety and Depression Scale that suggests the presence of a clinical mental health condition (Appendix 10).

Welfare of the Researcher

The supervisory team will be aware of the time and location of all focus groups and the researcher will follow the university's lone working policy for interviews being conducted in participant's homes. The researcher will provide the supervisory team with a sealed envelope containing the participants name and the address where the interview is taking place. The researcher will carry a mobile phone at all times to ensure they are contactable and their contact details will be provided to all members of the supervisory team. The team will be informed of the researcher's method of transport and approximate time the interview/focus group will be completed. The researcher will contact the team via text on arrival and will call to confirm when the interview has been completed. If the team does not receive a phone call within an hour of the estimated completion time and are unable to contact the researcher, they will open the sealed envelope and contact the authorities with the information. The emotional wellbeing of the researcher will also be considered, due to the emotional impact of working with a patient group with an end-stage illness, and debriefing will be provided by the supervisory team if needed (Social Research Association, 2001)

Dissemination of Results

The protocol for the study, findings from the systematic review, feasibility randomised controlled trial, process evaluation and economic evaluation will be submitted for publication

in high quality peer reviewed journals and presented at national and international conferences including the British Renal Symposium and the EDTNA/ERCA annual conference. Service users will also be involved in the dissemination of findings, and researchers will collaborate with the Northern Ireland Kidney Patient Association and Kidney Care UK. The economic evaluation data collection form will be listed on the MRC's Database of Instruments for Resource Use Measurement (DIRUM). A social media plan will be created to incorporate platforms such as Twitter and Facebook to disseminate information, progress, events and findings from the study.

References

Agus, A, Phair, G, Normand, C, Brazil, K, Burns, A, Roderick, P, Thompson, C, Maxwell, A, Yaqoob, M & Noble, H 2017, '*Cost of conservative management in patients with end stage kidney disease who decline dialysis: lessons from a multi-centre observational study in the UK*' Health Economics Association of Ireland Meeting, Belfast, United Kingdom, 18/09/2017, pp. 1.

All-Party Parliamentary Group on Arts Health and Wellbeing (2017a) *Creative Health: The Arts for Health and Wellbeing | The Short Report, All-Party Parliamentary Group on Arts Health and Wellbeing*.

All-Party Parliamentary Group on Arts Health and Wellbeing (2017b) 'The Arts for Health and Wellbeing | Inquiry Report', (July).

Allmark, P. *et al.* (2009) 'Ethical issues in the use of in-depth interviews: Literature review and discussion', *Research Ethics*, 5(2), pp. 48–54. doi: 10.1177/174701610900500203.

Annunziata, M. A., Muzzatti, B. and Altoé, G. (2011) 'Defining hospital anxiety and depression scale (HADS) structure by confirmatory factor analysis: A contribution to validation for oncological settings', *Annals of Oncology*, 22(10), pp. 2330–2333. doi: 10.1093/annonc/mdq750.

Arain, M. *et al.* (2010) 'What is a pilot or feasibility study? A review of current practice and editorial policy', *BMC Medical Research Methodology*, 10, pp. 1–7. doi: 10.1186/1471-2288-10-67.

- Arain, M. *et al.* (2016) ‘Feasibility and Pilot studies’, *Public Health Research*.
- Avery, K. N. L. *et al.* (2017) ‘Informing efficient randomised controlled trials: exploration of challenges in developing progression criteria for internal pilot studies’, *BMJ Open*, 7(2), p. e013537. doi: 10.1136/bmjopen-2016-013537.
- Barros, A. *et al.* (2016) ‘Depression, quality of life, and body composition in patients with end-stage renal disease: A cohort study’, *Revista Brasileira de Psiquiatria*, 38, pp. 301–306. doi: 10.1590/1516-4446-2015-1681.
- Beck, A. T. *et al.* (1988) ‘An inventory for measuring clinical anxiety: Psychometric properties.’, *Journal of Consulting and Clinical Psychology*. US: American Psychological Association, pp. 893–897. doi: 10.1037/0022-006X.56.6.893.
- Bowen, D. J. *et al.* (2009) ‘How we design feasibility studies’, *American Journal of Preventive Medicine*, 36(5), pp. 452–457. doi: 10.1016/j.amepre.2009.02.002.
- Boyce, M. *et al.* (2017) ‘The impact of the arts in healthcare on patients and service users: A critical review’, *Health and Social Care in the Community*, pp. 1–16. doi: 10.1111/hsc.12502.
- Braun, V. and Clarke, V. (2006) ‘Using thematic analysis in psychology’, *Qualitative Research in Psychology*, 3(2), pp. 77–101. doi: 10.1191/1478088706qp063oa.
- Bugge, C. *et al.* (2013) ‘A process for Decision-making after Pilot and feasibility Trials (ADePT): development following a feasibility study of a complex intervention for pelvic organ prolapse’, *Trials*, 14(353), pp. 1–13. doi: 10.1186/1745-6215-14-353.
- Bujang, M. A. *et al.* (2015) ‘Depression, anxiety and stress among patients with dialysis and the association with quality of life’, *Asian Journal of Psychiatry*. Elsevier B.V., 18, pp. 49–52. doi: 10.1016/j.ajp.2015.10.004.
- Bungay, H., Munn-Giddigs, C. and Wilson, C. (2014) *The Value of the Arts in Therapeutic and Clinical Interventions : A critical review of the literature*. Cambridge.
- Cao, X., Tian, L. and Lin, C. (2017) ‘Symptom clusters in patients receiving haemodialysis: a systematic review of observational studies’, *Journal of Clinical Nursing*, 26(17–18), pp. 2545–2557. doi: 10.1111/jocn.13644.
- Carlsen, B. and Glenton, C. (2011) ‘What about N? A methodological study of sample-size

reporting in focus group studies’, *BMC Medical Research Methodology*, 11(1), p. 26. doi: 10.1186/1471-2288-11-26.

Carter, N. *et al.* (2014) ‘The use of triangulation in qualitative research’, *Oncology Nursing Forum*, 41(5), pp. 545–547. doi: 10.1188/14.ONF.545-547.

CASP UK (2017) *CASP Tools & Checklists*. Available at: <http://www.casp-uk.net/casp-tools-checklists> (Accessed: 7 February 2018).

Centre for Arts in Medicine (2017) ‘Talking about Arts in Health: A white paper addressing the language used to describe the discipline from a higher education perspective’, pp. 1–24. Available at: http://arts.ufl.edu/site/assets/files/106496/uf_cam_language_whitepaper.pdf.

Chen, S.-F., Wang, I.-J. and Lang, H.-C. (2016) ‘Risk of major depression in patients with chronic renal failure on different treatment modalities: A matched-cohort and population-based study in Taiwan.’, *Hemodialysis international. International Symposium on Home Hemodialysis*, 20(1), pp. 98–105. doi: 10.1111/hdi.12334.

Chilcot, J. *et al.* (2011) ‘An association between depressive symptoms and survival in incident dialysis patients’, *Nephrology Dialysis Transplantation*, 26(5), pp. 1628–1634. doi: 10.1093/ndt/gfq611.

Cleemput, I. *et al.* (2004) ‘The construct and concurrent validity of the EQ-5D in a renal transplant population’, *Value in Health. International Society for Pharmacoeconomics and Outcomes Research (ISPOR)*, 7(4), pp. 499–509. doi: 10.1111/j.1524-4733.2004.74013.x.

Cohen, S. D. *et al.* (2007) ‘Screening, diagnosis, and treatment of depression in patients with end-stage renal disease’, *Clinical Journal of the American Society of Nephrology*, 2(6), pp. 1332–1342. doi: 10.2215/CJN.03951106.

Cohen, S. D., Cukor, D. and Kimmel, P. L. (2016) ‘Anxiety in patients treated with hemodialysis’, *Clinical Journal of the American Society of Nephrology*, 11(12), pp. 2250–2255. doi: 10.2215/CJN.02590316.

Connolly, P. (2003) ‘Ethical principles for researching vulnerable groups’, *University of Ulster, Coleraine*, (May). doi: <http://www.ofmdfmi.gov.uk/publication-az>.

Craemer, R. (2009) ‘The arts and health: From economic theory to cost-effectiveness’, *The University of Melbourne Refereed e-Journal*, 1(4), pp. 1–14.

Crone, D. M. *et al.* (2012) 'It helps me make sense of the world: The role of an art intervention for promoting health and wellbeing in primary care-perspectives of patients, health professionals and artists', *Journal of Public Health (Germany)*, 20(5), pp. 519–524. doi: 10.1007/s10389-012-0495-x.

Cukor, D. *et al.* (2008) 'Course of depression and anxiety diagnosis in patients treated with hemodialysis: A 16-month follow-up', *Clinical Journal of the American Society of Nephrology*, 3(6), pp. 1752–1758. doi: 10.2215/CJN.01120308.

Data Protection Act 2018 (2018). Queen's Printer of Acts of Parliament. Available at: <http://www.legislation.gov.uk/ukpga/2018/12/contents/enacted> (Accessed: 7 June 2018).

Denhaerynck, K. *et al.* (2007) 'Prevalence and Consequences of Nonadherence to Hemodialysis Regimens', *American Journal of Critical Care*, 16(3).

Donovan, J. L. *et al.* (2014) 'The intellectual challenges and emotional consequences of equipoise contributed to the fragility of recruitment in six randomized controlled trials', *Journal of Clinical Epidemiology*. Elsevier Inc, 67(8), pp. 912–920. doi: 10.1016/j.jclinepi.2014.03.010.

Dowrick, C. *et al.* (2012) 'Get into reading as an intervention for common mental health problems: Exploring catalysts for change', *Medical Humanities*, 38(1), pp. 15–20. doi: 10.1136/medhum-2011-010083.

Eldridge, S. M., Chan, C. L., *et al.* (2016) 'CONSORT 2010 statement: extension to randomised pilot and feasibility trials', *Pilot and Feasibility Studies*, 2(1), p. 64. doi: 10.1186/s40814-016-0105-8.

Eldridge, S. M., Lancaster, G. A., *et al.* (2016) 'Defining feasibility and pilot studies in preparation for randomised controlled trials: Development of a conceptual framework', *PLoS ONE*, 11(3), pp. 1–22. doi: 10.1371/journal.pone.0150205.

Fancourt, D. (2017) *Arts in health : designing and researching interventions*. Oxford: Oxford University Press.

Farnell, S. and Dawson, D. (2006) "'It's not like the wards": Experiences of nurses new to critical care: A qualitative study', *International Journal of Nursing Studies*, 43(3), pp. 319–331. doi: 10.1016/j.ijnurstu.2005.04.007.

Farragher, J. F., Polatajko, H. J. and Jassal, S. V. (2017) ‘The relationship between fatigue and depression in adults with end-stage renal disease on chronic in-hospital hemodialysis: A scoping review’, *Journal of Pain and Symptom Management*. Elsevier Inc, 53(4), p. 783–803.e1. doi: 10.1016/j.jpainsymman.2016.10.365.

Forman, J. *et al.* (2017) ‘Development and application of the RE-AIM QuEST mixed methods framework for program evaluation’, *Preventive Medicine Reports*. Elsevier B.V., 6, pp. 322–328. doi: 10.1016/j.pmedr.2017.04.002.

Francis, J. J. *et al.* (2010) ‘What is an adequate sample size? Operationalising data saturation for theory-based interview studies’, *Psychology and Health*, 25(10), pp. 1229–1245. doi: 10.1080/08870440903194015.

García-Llana, H. *et al.* (2014) ‘El papel de la depresión, la ansiedad, el estrés y la adhesión al tratamiento en la calidad de vida relacionada con la salud en pacientes en diálisis: Revisión sistemática de la literatura’, *Nefrología*, 34(5), pp. 637–657. doi: 10.3265/Nefrologia.pre2014.Jun.11959.

Glasgow, R. E. and Estabrooks, P. E. (2018) ‘Pragmatic applications of RE-AIM for health care initiatives in community and clinical settings’, *Preventing Chronic Disease: Public Health Research, Practice, and Policy Chronic Disease*, 15(E02), pp. 1–7. doi: 10.5888/pcd15.170271.

Glover, C. *et al.* (2011) ‘Understanding and assessing the impact of end-stage renal disease on quality of life’, *Patient*, 4(1), pp. 19–30.

Grant, A. *et al.* (2013) ‘Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting’, *Trials*, 14(1), p. 15. doi: 10.1186/1745-6215-14-15.

Green, J. and Thorogood, N. (2004) *Qualitative methods for health research*. London: Sage Publications.

Guest, G., Bunce, A. and Johnson, L. (2006) ‘How many interviews are enough?’, *Field Methods*, 18(1), pp. 59–82. doi: 10.1177/1525822X05279903.

Haigh, C. and Witham, G. (2015) ‘Distress Protocol for qualitative data collection’, *Manchester Metropolitan University*, pp. 1–4. Available at:

<https://www2.mmu.ac.uk/media/mmuacuk/content/documents/rke/Advisory-Distress-Protocol.pdf>.

Hanson, L. C. *et al.* (2015) 'Strategies to support recruitment of patients with life-limiting illness for research: The palliative care research cooperative group', *Journal of Pain and Symptom Management*, 48(6), pp. 1021–1030. doi: 10.1016/j.jpainsymman.2014.04.008.Strategies.

Health & Care Professions Council (2009) *What is an Arts therapist?* Available at: <http://www.hcpc-uk.co.uk/assets/documents/10004B66Arts-therapy.pdf> (Accessed: 2 November 2017).

Hoffmann, T. C. *et al.* (2014) 'Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide', *BMJ (Online)*, 348, pp. 1–12. doi: 10.1136/bmj.g1687.

Hounsome, N. and Shearer, J. (2015) *What kind of health economic input is appropriate in a feasibility study?*, *National Institute for Health Research*. Available at: <http://www.rds-london.nihr.ac.uk/How-to-design-a-study-find-funding/Health-economics/Health-economics-feasibility-study.aspx> (Accessed: 26 November 2017).

Hunter, R. and Shearer, J. (2014) *Cost-consequences analysis - an underused method of economic evaluation*, *National Institute for Health Research*. Available at: <http://www.rds-london.nihr.ac.uk/How-to-design-a-study-find-funding/Health-economics/Cost-consequences-analysis.aspx> (Accessed: 26 November 2017).

Jugder, N. (2016) 'The thematic analysis of interview data : an approach used to examine the influence of the market on curricular provision in Mongolian higher education institutions', *Hillary Place Papers*, pp. 1–7. Available at: <http://2gupzkho2c1wvo8kk58b6cpr.wpengine.netdna-cdn.com/files/2016/02/HPP2016-3-Jugder.pdf>.

Julious, S. A. (2005) 'Sample size of 12 per group rule of thumb for a pilot study', *Pharmaceutical Statistics*, 4(4), pp. 287–291. doi: 10.1002/pst.185.

Kang, G. W. *et al.* (2015) 'Clinical and psychosocial factors predicting health-related quality of life in hemodialysis patients', *Hemodialysis International*, 19(3), pp. 439–446. doi: 10.1111/hdi.12271.

- Kannan, S. and Gowri, S. (2015) 'Pilot studies: Are they appropriately reported?', *Perspectives in Clinical Research*, 6(4), p. 207. doi: 10.4103/2229-3485.167097.
- Kim, K. S., Loring, S. and Kwekkeboom, K. (2017) 'Use of art-making intervention for pain and quality of life among cancer patients: A systematic review', *Journal of Holistic Nursing*, pp. 1–13. doi: 10.1177/0898010117726633.
- Kim, Y., Evangelista, L. S. and Park, Y.-G. Y.-G. (2015) 'Anxiolytic effects of music interventions in patients receiving incenter hemodialysis: A systematic review and meta-analysis.', *Nephrology nursing journal : journal of the American Nephrology Nurses' Association*. United States, 42(4), pp. 339–348. doi: 10.1007/s10459-010-9231-x.
- Kokoszka, A., Leszczyńska, K. and Radzio, R. (2016) 'Prevalence of depressive and anxiety disorders in dialysis patients with chronic kidney disease', *Archives of Psychiatry and Psychotherapy*, 1, pp. 8–13. doi: 10.12740/APP/61977.
- Komorowski, M. and Raffa, J. (2016) 'Markov models and cost effectiveness analysis: Applications in medical research', in Data, M. I. T. C. (ed.) *Secondary Analysis of Electronic Health Records*. Cambridge: Springer International Publishing, pp. 351–367. doi: 10.1007/978-3-319-43742-2_24.
- Kraemer, H. C. *et al.* (2006) 'Caution regarding the use of pilot studies to guide power calculations for study proposals', *Archives of General Psychiatry*, 63(5), pp. 484–489. doi: 10.1001/archpsyc.63.5.484.
- Lancaster, G. A., Dodd, S. and Williamson, P. R. (2004) 'Design and analysis of pilot studies: Recommendations for good practice', *Journal of Evaluation in Clinical Practice*, 10(2), pp. 307–312. doi: 10.1111/j..2002.384.doc.x.
- Levati, S. *et al.* (2016) 'Optimisation of complex health interventions prior to a randomised controlled trial: a scoping review of strategies used', *Pilot and Feasibility Studies*. *Pilot and Feasibility Studies*, 2(1), p. 17. doi: 10.1186/s40814-016-0058-y.
- Liebman, S., Li, N.-C. and Lacson, E. (2016) 'Change in quality of life and one-year mortality risk in maintenance dialysis patients', *Quality of Life Research*. Springer International Publishing, 25(9), pp. 2295–2306. doi: 10.1007/s11136-016-1257-y.
- Loosman, W. L. *et al.* (2010) 'Validity of the Hospital Anxiety and Depression Scale and the

Beck Depression Inventory for use in end-stage renal disease patients', *British Journal of Clinical Psychology*, 49(4), pp. 507–516. doi: 10.1348/014466509X477827.

Loosman, W. L. *et al.* (2015) 'Association of depressive and anxiety symptoms with adverse events in Dutch chronic kidney disease patients: A prospective cohort study', *BMC Nephrology*. *BMC Nephrology*, 16(1), pp. 1–8. doi: 10.1186/s12882-015-0149-7.

Lowney, A. C. *et al.* (2015) 'Understanding what influences the health-related quality of life of hemodialysis patients: A collaborative study in England and Ireland', *Journal of Pain and Symptom Management*. Elsevier Inc, 50(6), pp. 778–785. doi: 10.1016/j.jpainsymman.2015.07.010.

Maung, S. *et al.* (2017) 'Sleep disturbance and depressive affect in patients treated with haemodialysis', *Journal of Renal Care*, 43(1), pp. 60–66. doi: 10.1111/jorc.12188.

May, C. (2013) 'Towards a general theory of implementation', *Implementation Science*, 8(1), p. 18. doi: 10.1186/1748-5908-8-18.

Mc Daid, C. *et al.* (2006) 'Increasing participation of cancer patients in randomised controlled trials: A systematic review', *Trials*, 7, pp. 1–10. doi: 10.1186/1745-6215-7-16.

Mccann, K. *et al.* (2000) 'Fatigue in persons with renal failure who require maintenance haemodialysis', *Journal of Advanced Nursing*, 32(5), pp. 1132–1142. doi: jan1584 [pii].

McConnell, T. *et al.* (2016) 'Evaluation of the effectiveness of music therapy in improving the quality of life of palliative care patients: a randomised controlled pilot and feasibility study', *BMJ Supportive & Palliative Care* . Pilot and Feasibility Studies, 6(3), p. 398. doi: 10.1136/bmjspcare-2016-001204.37.

Medical Research Council (2009) *Developing and evaluating complex interventions: new guidance*, Medical Research Council.

Momennasab, M. *et al.* (2018) 'Comparing the effect of listening to music during hemodialysis and at bedtime on sleep quality of hemodialysis patients: A randomized clinical trial', *European Journal of Integrative Medicine*. S.S. Najafi, Department of Nursing, School of Nursing and Midwifery, Shiraz University of Medical Sciences, Shiraz, Iran, Islamic Republic of. E-mail: najafisa@sums.ac.ir; Elsevier GmbH (E-mail: info@elsevier-deutschland.de), 17, pp. 86–91. doi: <http://dx.doi.org/10.1016/j.eujim.2017.12.001>.

Moore, G. *et al.* (2014) 'Process evaluation of complex interventions', *Medical Research Council*, p. 222.

Moore, G. F. *et al.* (2015) 'Process evaluation of complex interventions: Medical Research Council guidance', *BMJ*, 350, pp. h1258–h1258. doi: 10.1136/bmj.h1258.

Nabolsi, M. M., Wardam, L. and Al-Halabi, J. O. (2015) 'Quality of life, depression, adherence to treatment and illness perception of patients on haemodialysis', *International Journal of Nursing Practice*, 21, pp. 1–10. doi: 10.1111/ijn.12205.

National Institute for Health and Care Excellence (2012) *Assessing cost effectiveness | Guidance and guidelines | NICE*. NICE. Available at: <https://www.nice.org.uk/process/pmg6/chapter/assessing-cost-effectiveness> (Accessed: 26 November 2017).

National Institute for Health and Care Excellence (2014) *Chronic kidney disease in adults: assessment and management | Guidance and guidelines | NICE*. NICE. Available at: <https://www.nice.org.uk/guidance/cg182/chapter/1-Recommendations#classification-of-chronic-kidney-disease-2> (Accessed: 10 November 2017).

O’Cathain, A. *et al.* (2014) 'Maximising the value of combining qualitative research and randomised controlled trials in health research: The QUALitative Research in Trials (QUART) study - A mixed methods study', *Health Technology Assessment*, 18(38), pp. 1–197. doi: 10.3310/hta18380.

Ogden, J. (2017) 'QALYs and their role in the NICE decision-making process', *Prescriber*, 28(4), pp. 41–43. doi: 10.1002/psb.1562.

Ossareh, S., Tabrizian, S. and Zebarjadi, M. (2014) 'Prevalence of depression in maintenance hemodialysis patients and its correlation with adherence to medications', *Iranian journal of kidney diseases*, 8(6), pp. 467–475. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/25362222>.

Palmer, S. C., Sciancalepore, M. and Strippoli, G. F. M. (2011) 'Trial quality in nephrology: How are we measuring up?', *American Journal of Kidney Diseases*. Elsevier Inc., 58(3), pp. 335–337. doi: 10.1053/j.ajkd.2011.06.006.

Peterson, J. C. *et al.* (2012) 'Attrition in longitudinal randomized controlled trials: Home

visits make a difference', *BMC Medical Research Methodology*, 12, pp. 1–12. doi: 10.1186/1471-2288-12-178.

Pompili, M. *et al.* (2013) 'Suicide risk in dialysis: Review of current literature', *The International Journal of Psychiatry in Medicine*, 46(1), pp. 85–108. doi: 10.2190/PM.46.1.f.

Preljevic, V. T. *et al.* (2013) 'Anxiety and depressive disorders in dialysis patients: Association to health-related quality of life and mortality', *General Hospital Psychiatry*. Elsevier Inc., 35(6), pp. 619–624. doi: 10.1016/j.genhosppsy.2013.05.006.

Raj, R. *et al.* (2017) 'Symptoms and their recognition in adult haemodialysis patients: Interactions with quality of life', *Nephrology*, (22), pp. 228–233. doi: 10.1111/nep.12754.

Schneider, M. *et al.* (2009) 'Rationale, design and methods for process evaluation in the HEALTHY study', *International Journal of Obesity*, 33(Suppl 4), pp. S60–S67. doi: 10.1038/ijo.2009.118.Rationale.

Sim, J. and Lewis, M. (2012) 'The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency', *Journal of Clinical Epidemiology*. Elsevier Inc, 65(3), pp. 301–308. doi: 10.1016/j.jclinepi.2011.07.011.

Skingley, A. *et al.* (2011) 'The effectiveness and cost-effectiveness of a participative community singing programme as a health promotion initiative for older people: protocol for a randomised controlled trial', *BMC Public Health*, 11(1), p. 142. doi: 10.1186/1471-2458-11-142.

Social Research Association (2001) 'A Code of Practice for the Safety of Social Researchers', *Safety of Social Researchers*, pp. 1–8. Available at: http://the-sra.org.uk/sra_resources/safety-code/.

Sonke, J. *et al.* (2015) 'The effects of arts-in-medicine programming on the medical-surgical work environment', *Arts and Health*. Taylor & Francis, 7(1), pp. 27–41. doi: 10.1080/17533015.2014.966313.

Sonke, J. (2017) 'Nurse perceptions of artists as collaborators in interprofessional care teams', *Healthcare*, 5(50), pp. 1–14. doi: 10.3390/healthcare5030050.

Staricoff, R. and Clift, S. (2011) *Arts and Music in Healthcare : An overview of the medical literature: 2004-2011*. London.

- Steinke, I. (2004) 'Quality criteria in qualitative research', *A companion to qualitative research*, pp. 184–190. doi: 10.4135/9781412979306.n259.
- Sturm, I. *et al.* (2014) 'Effect of dance on cancer-related fatigue and quality of life.', *Supportive Care in Cancer*. Germany, 22(8), pp. 2241–2249. doi: <https://dx.doi.org/10.1007/s00520-014-2181-8>.
- Suresh, K. (2011) 'An overview of randomization techniques: An unbiased assessment of outcome in clinical research.', *Journal of human reproductive sciences*. Wolters Kluwer -- Medknow Publications, 4(1), pp. 8–11. doi: 10.4103/0974-1208.82352.
- Teare, M. *et al.* (2014) 'Sample size requirements to estimate key design parameters from external pilot randomised controlled trials: a simulation study', *Trials*, 15(1), p. 264. doi: 10.1186/1745-6215-15-264.
- The Joanna Briggs Institute (2017) *Critical Appraisal Tools*. Available at: <http://joannabriggs.org/research/critical-appraisal-tools.html> (Accessed: 15 January 2018).
- Tracy, S. J. (2013) *Qualitative research methods : collecting evidence, crafting analysis, communicating impact*. Chichester : Wiley-Blackwell.
- Valdez, A. M. (2008) 'Transitioning from novice to competent: What can we learn from the literature about graduate nurses in the emergency setting?', *Journal of Emergency Nursing*, 34(5), pp. 435–440. doi: 10.1016/j.jen.2007.07.008.
- Vasilopoulou, C. *et al.* (2015) 'The impact of anxiety and depression on the quality of life of hemodialysis patients', *Global Journal of Health Science*, 8(1), p. 45. doi: 10.5539/gjhs.v8n1p45.
- Wan Zukiman, W. Z. H. *et al.* (2017) 'Symptom prevalence and the negative emotional states in end-stage renal disease patients with or without renal replacement therapy: A cross-sectional analysis.', *Journal of Palliative Medicine*. Department of Medicine, Universiti Kebangsaan Malaysia Medical Centre, Kuala Lumpur, Malaysia.: Mary Ann Liebert, Inc., 20(10), pp. 1127–1134. doi: 10.1089/jpm.2016.0450.
- Watnick, S. *et al.* (2003) 'The prevalence and treatment of depression among patients starting dialysis', *American Journal of Kidney Diseases*, 41(1), pp. 105–110. doi: 10.1053/ajkd.2003.50029.

Wilson, C. *et al.* (2015) 'Healthcare professionals' perceptions of the value and impact of the arts in healthcare settings: A critical review of the literature', *International Journal of Nursing Studies*. Elsevier Ltd, 56, pp. 90–101. doi: 10.1016/j.ijnurstu.2015.11.003.

Wuerth, D., Finkelstein, S. H. and Finkelstein, F. O. (2008) 'Psychosocial factors in patients with chronic kidney disease: The identification and treatment of depression in patients maintained on dialysis', *Seminars in Dialysis*, 18(2), pp. 142–146. doi: 10.1111/j.1525-139X.2005.18213.x.

Ziegelstein, R. C. *et al.* (2000) 'Patients with depression are less likely to follow recommendations to reduce cardiac risk during recovery from a myocardial infarction.', *Archives of internal medicine*, 160(12), pp. 1818–1823. doi: 10.1001/archinte.160.12.1818.

Zyoud, S. H. *et al.* (2016) 'Factors affecting quality of life in patients on haemodialysis: a cross-sectional study from Palestine', *BMC Nephrology*. BMC Nephrology, 17(1), p. 44. doi: 10.1186/s12882-016-0257-z.

Appendix 1: Participant information sheet Phase 2



Developing an arts-based intervention for patients with end-stage kidney disease receiving haemodialysis

Participant information sheet –Feasibility Trial

We would like to invite you take part in a research study. Before you decide whether to take part it is important for you to understand what the research will involve and why it is being done. Please take time to read this information sheet carefully and discuss it with friends and family if you wish. You can choose to decide whether or not take part in this research, and if you decide not to take part it will not affect the care that you receive from your own healthcare team. Ask us if you have any questions or would like more information.

CONTENTS

Part 1: What is the study and why is it being carried out?

Part 2: What does the study involve?

Part 3: Important information

Part 1: What is the study and why is it being carried out?

What is the purpose of the study?

Haemodialysis is a time-consuming treatment that requires people to spend a significant amount of time in hospital. Arts activities can be used in hospitals to help patients fill their time with something that is creative and enjoyable. The purpose of this study is to explore the best way of delivering artistic activities to patients who are receiving haemodialysis, whether these activities can improve mood and wellbeing, and how this can be measured in future studies.

Why have I been asked to take part in this study?

1. You are attending the Antrim Area Hospital's Renal Unit and are currently receiving haemodialysis
2. We would like to know whether art can be beneficial for patients receiving haemodialysis

Do I have to take part?

It is your decision whether to take part in this study or not. If you would like to take part you will be asked to keep this information sheet and sign a consent form. If you decide to take part you are able to withdraw at any time, and you do not need to provide a reason. Deciding to withdraw from the study will not impact on the standard of care you receive.

Part 2: What does the study involve?

How will the research be carried out?

The research is a 'randomised controlled trial'. This means that when someone chooses to take part they are assigned at random to either take part in the artistic activity or not. This allows us to compare the people who take part in the activity to those who did not. A small number of people will be asked to consider doing an interview about their experience of the study.

What will happen if I decide to take part in the study?

- You will be asked to sign a consent form and will then be asked to complete three questionnaires (about your quality of life, symptoms, and mood).
- People will be assigned at random to take part in art, and will be offered a selection of artistic activities to choose from. You can choose whatever activity you feel you would enjoy the most. You will be asked to take part in this activity during your dialysis sessions over the course of three weeks.
- People assigned at random to not receive the intervention will attend the clinic as usual, and this will not affect the care that you receive from your own healthcare team.
- You will be asked to complete the three questionnaires at the start of the study, then three weeks, six weeks and three months after joining the study. This will happen during your regular visits to the hospital, so you will not need to make any extra trips to the hospital.
- You will also be asked to keep track of your hospital or GP visits during the study.
- We will ask to interview a small number of people about their experiences of the study.
- During the course of the study it is possible you may become unwell and be unable to complete the activity or the questionnaires. If this happens we would like to use the data you have already given us, with your consent.

Will any other information be collected?

We will ask you some questions about your occupation and education. We will also ask you about your medical history, diagnosis, medication and use of health services.

How long will the research last?

Most people will be in the study for three months.

What are the possible disadvantages of taking part?

We may ask you to take part in an artistic activity during haemodialysis sessions. We will try to make the activities easy, engaging and fun. It may seem strange or uncomfortable to take part in an arts activity in a clinical setting, and you may be worried it will affect your dialysis. The range of activities have been reviewed by an advisory group that includes patients, staff and artists who work in clinical settings, to ensure that they're safe, appropriate for the dialysis unit and won't impact your treatment.

We will ask you to complete questionnaires over the 3 month period you are in the study. The questionnaires cover subjects that you may find intrusive or upsetting to talk about, including symptoms you're experiencing, their impact on your life relationships and your mental health. You can choose not to answer any questions you do not feel comfortable answering and this will not affect your treatment or participation in the study. We will help you fill out these questionnaires and try and make this a quick and easy task, but if you feel you need additional emotional support we will be able to direct you to supportive services.

What are the possible benefits of taking part?

We cannot promise that this study will help you, but many people find art enjoyable and find that it improves their mood and reduces anxiety. Taking part in artistic activities can also help distract people from unpleasant symptoms and medical treatments. Even if you are not allocated to the group who participates in art, people who take part in research also can feel a sense of satisfaction as they are helping improve the care of others.

Due to the need to reduce the spread of infection in the clinical setting any arts supplies that are used will not be shared throughout the unit, because of this the art supplies will be your own and at the end of the study you will be able to keep these for your own use. If you have been randomly assigned to the comparison group and won't be taking part in the arts activities during the study, we will provide you with a packet of identical arts supplies on completion of the study so you can take part in arts activities in your own time.

Important information

What will happen if I don't want to carry on with the study?

Involvement in the study is completely voluntary and you can decide to stop at any point. You do not need to provide a reason for leaving the study. If you decide to leave we will ask if we can use the information that you have already provided, it is your choice whether to say yes or no.

What if I become ill during the study and cannot speak for myself?

We will ask for your permission at the start of the study to use the information that we have collected up until this point. If you become ill and cannot speak for yourself we will not collect any further information from you, and will only use the information in ways you had already agreed to.

How will the researchers keep my information confidential?

Any confidential written information will be stored in locked filing cabinets, in a locked office, at Queen's University and will be destroyed after five years. All digital information will be stored on secure servers and will be password protected. Any identifiable information, including your name and address, will be removed. The results of this research will be published but will not include any information that will allow people to identify those who participated. If you have provided information that causes the researcher to be concerned about your wellbeing or the wellbeing of a child, we will discuss this with you and an appropriate third party may need to be informed.

What will happen to the results of the research?

The results of this study will be published in peer-reviewed journals, presented at research conferences and will form a final PhD thesis. If you are interested we can provide you with a summary of results once data analysis has finished, and you can contact the research team if you would like a copy of any publications. The hope is that these results will inform a larger study and influence policy and practice.

Who funding and carrying out this research?

This study is part of a PhD project funded by the Department for the Economy (DfE). It is being carried out by Claire Carswell, a registered mental health nurse at Queen's University Belfast. Her supervision team includes Dr Helen Noble, Professor Joanne Reid and Dr Ian Walsh

Who has reviewed the study?

This research has been reviewed by an independent Research Ethics Committee that is responsible for protecting the rights and safety of research participants. This study has been given a favourable opinion by the Office of Research Ethics Committees for Northern Ireland.

Who do I contact for further information?

If you have any questions or would like further information please feel free to contact:

Claire Carswell
Telephone: 028 9097 5766
Email: ccarswell02@qub.ac.uk

School of Nursing and Midwifery

Queen's University Belfast

Medical Biology Centre

Dr Helen Noble
Telephone: 028 9097 2472
Email: helen.noble@qub.ac.uk

97 Lisburn Road

Belfast BT9 7BL

Professor Joanne Reid
Telephone: 028 9097 2459
Email: j.reid@qub.ac.uk

Dr Ian Walsh
Telephone: 028 9097 8983
Email: i.walsh@qub.ac.uk

Complaints procedure

If you have any complaints about the research or a member of the research team you have the right to complain. If you don't wish to discuss your complaint with a member of the research team or your own healthcare team, please contact:

The Complaints Department
Bush House
Bush Road
Antrim
BT41 2QB
Tel: 0289442655
E-mail: user.feedback@northerntrust.hscni.net

Appendix 2: Participant consent form Phase 2



Patient Consent form – Feasibility Trial

Study Title: Developing an arts-based intervention in patients with end-stage kidney disease receiving haemodialysis

Name of Researcher: Claire Carswell

		Please initial box
1	I confirm that I have read the information sheet dated 04.07.18, version 0.4 for the above study. I have had the opportunity to consider the information, ask questions, and had my questions answered fully.	
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without having my care affected.	
3	I understand that the study is being conducted as part of a PhD project from Queen’s University Belfast and that my personal information will be held securely on the university premises and will be handled according to the Data Protection Act 2018	
4	I understand that data collected as part of this may be looked at by authorized individuals from Queen’s University Belfast where it is relevant to my taking part in this research. I give permission for these individuals to have access to this information.	
5	I agree to take part in the above study.	

Name of participant

Date

Signature

Researcher

Date

Signature

Anonymous ID code:	
--------------------	--

Appendix 3: Participant information sheet – Patient Phase 3



Developing an arts-based intervention for patients with end-stage kidney disease receiving haemodialysis

Participant information sheet –Process Evaluation Interviews

We would like to invite you take part in a research study. Before you decide whether to take part it is important for you to understand what the research will involve and why it is being done. Please take time to read this information sheet carefully and discuss it with friends and family if you wish. You can choose to decide whether or not take part in this research, and if you decide not to take part it will not affect the care that you receive from your own healthcare team. Ask us if you have any questions or would like more information.

CONTENTS

Part 1: What is the study and why is it being carried out?

Part 2: What does the study involve?

Part 3: Important information

Part 1: What is the study and why is it being carried out?

What is the purpose of the study?

Haemodialysis is a time-consuming treatment that requires people to spend a significant amount of time in hospital. Arts activities can be used in hospitals to help patients fill their time with something that is creative and enjoyable. The purpose of this study is to explore the best way of delivering artistic activities to patients who are receiving haemodialysis and how best to carry out research in this area.

Why have I been asked to take part in this study?

1. You are attending the Antrim Area Hospital's Renal Unit and are currently receiving haemodialysis
2. You are taking part in the randomised controlled trial.

Do I have to take part?

It is your decision whether to take part in this study or not. If you would like to take part you will be asked to keep this information sheet and sign a consent form. If you decide to take part you are able to withdraw at any time, and you do not need to provide a reason. Deciding to withdraw from the study will not impact on the standard of care you receive.

Part 2: What does the study involve?

How will the research be carried out?

This part of the research is a 'process evaluation', this means we are gathering information on peoples experiences of the intervention and how it is being researched.

What will happen if I decide to take part in the study?

The researcher will arrange to meet with you to ask you some questions about your experiences relating to the intervention or the randomised controlled trial. For example, we are interested in why people decided to take part in the trial, what participants thought of the intervention and experiences of being part of a control group. Before the interview starts we will ask you to sign a consent form saying you are happy to take part in the process evaluation. To make sure the information is accurate we will record the interview. However you can ask us to stop recording at any time. The interview should not take any longer than 60 minutes. The interview can be carried out in your own home, at a place of your choosing or via telephone.

What are the possible benefits of taking part?

We cannot promise that this study will help you directly. However the results of this study will improve how the intervention is delivered and how future studies are carried out. Any relevant results will be presented to managers and staff so that service provision for patients with end-stage kidney disease receiving haemodialysis may be developed.

Important information

What will happen if I don't want to carry on with the study?

Involvement in the study is completely voluntary and you can decide to stop at any point. You do not need to provide a reason for leaving the study. If you decide to withdraw we will not use any information that we have collected from you.

What if I become distressed during the interview?

The interview process has the potential to be distressing for you. Therefore if you would like to pause the interview the researcher will stop recording, and before starting again will ask you if you feel okay to continue. If the researcher feels you are too distressed they will discontinue the interview. If you feel you need further support after the interview the researcher will provide you with an information pack of support services you can access.

How will the researchers keep my information confidential?

Any confidential written information will be stored in locked filing cabinets, in a locked office, at Queen's University and will be destroyed after five years. All digital information will be stored on secure servers and will be password protected. Any identifiable information, including your name and address, will be removed. The results of this research will be published but will not include any information that will allow people to identify those who participated. If you have provided information that causes the researcher to be concerned about your wellbeing or the wellbeing of a child, we will discuss this with you and an appropriate third party may need to be informed.

What will happen to the results of the research?

The results of this study will be published in peer-reviewed journals, presented at research conferences and will form a final PhD thesis. If you are interested we can provide you with a

summary of results once data analysis has finished, and you can contact the research team if you would like a copy of any publications. The hope is that these results will inform a larger study and influence policy and practice.

Who is funding and carrying out this research?

This study is part of a PhD project funded by the Department for the Economy (DfE). It is being carried out by Claire Carswell, a registered mental health nurse at Queen’s University Belfast. Her supervision team includes Dr Helen Noble, Professor Joanne Reid and Dr Ian Walsh

Who has reviewed the study?

This research has been reviewed by an independent Research Ethics Committee that is responsible for protecting the rights and safety of research participants. This study has been given a favourable opinion by the Office of Research Ethics Committees for Northern Ireland.

Who do I contact for further information?

If you have any questions or would like further information please feel free to contact:

Claire Carswell
Telephone: 028 9097 5766
Email: ccarswell02@qub.ac.uk

School of Nursing and Midwifery
Queen's University Belfast

Dr Helen Noble
Telephone: 028 9097 2472
Email: helen.noble@qub.ac.uk

Medical Biology Centre
97 Lisburn Road
Belfast BT9 7BL

Professor Joanne Reid
Telephone: 028 9097 2459
Email: j.reid@qub.ac.uk

Dr Ian Walsh
Telephone: 028 9097 8983
Email: i.walsh@qub.ac.uk

Complaints procedure

If you have any complaints about the research or a member of the research team you have the right to complain. If you don’t wish to discuss your complaint with a member of the research team or your own healthcare team, please contact:

The Complaints Department
Bush House
Bush Road
Antrim
BT41 2QB
Tel: 0289442655
E-mail: user.feedback@northerntrust.hscni.net

Appendix 4: Participant consent form – Patient Phase 3



Patient Consent form – Process evaluation - Interview

Study Title: Developing an arts-based intervention in patients with end-stage kidney disease receiving haemodialysis

Name of Researcher: Claire Carswell

		Please initial box
1	I confirm that I have read the information sheet dated 23.3.18, version 0.3 for the above study. I have had the opportunity to consider the information, ask questions, and had my questions answered fully.	
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without having my care affected.	
3	I understand that the study is being conducted as part of a PhD project from Queen's University Belfast and that my personal information will be held securely on the university premises and will be handled according to the Data Protection Act 2018	
4	I understand that data collected as part of this study may be looked at by authorized individuals from Queen's University Belfast where it is relevant to my taking part in this research. I give permission for these individuals to have access to this information.	
5	I understand the interviews will be tape recorded and there is a possibility of direct quotation being used in publications.	
6	I understand that what is discussed during the interviews is confidential with the exception that if I disclose information that indicates that I am at risk of harming myself or others, or in danger of being harmed by someone else, the researcher is legally obliged to pass on this information to the relevant authority	
7	I agree to take part in the interview.	

Name of participant

Date

Signature

Researcher

Date

Signature

Anonymous ID code:	
--------------------	--

Appendix 5: Participant information sheet – Healthcare staff Phase 3



Developing an arts-based intervention for patients with end-stage kidney disease receiving haemodialysis

Participant information sheet – HCP Process Evaluation Focus Group

We would like to invite you take part in a research study. Before you decide whether to take part it is important for you to understand what the research will involve and why it is being done. Please take time to read this information sheet carefully and discuss it with friends and family if you wish.

You can choose to decide whether or not take part in this research, and if you decide not to take part it will not affect the care that you receive from your own healthcare team. Ask us if you have any questions or would like more information.

CONTENTS

Part 1: What is the study and why is it being carried out?

Part 2: What does the study involve?

Part 3: Important information

Part 1: What is the study and why is it being carried out?

What is the purpose of the study?

Haemodialysis is a time-consuming treatment that requires people to spend a significant amount of time in hospital. Arts activities can be used in hospitals to help patients fill their time with something that is creative and enjoyable. The purpose of this study is to explore the best way of delivering arts activities to patients who are receiving haemodialysis, and how we can best measure the benefits of these activities. It is important to consider the setting where these activities are taking place and examine how they may affect the working environment for healthcare staff.

Why have I been asked to take part in this study?

You have been selected to take part as you are a healthcare professional working in the haemodialysis unit where we are carrying out research exploring the use of art within the clinical setting.

Do I have to take part?

It is your decision whether to take part in this study or not. If you decide to take part you are able to withdraw at any time, and you do not need to provide a reason.

Part 2: What does the study involve?

How will the research be carried out?

This research is a process evaluation, this means we are talking to people to gather information on their experiences of an intervention (the arts activities) and how it is being researched and evaluated.

What will happen if I decide to take part in the study?

If you decide to participate in this research you will take part in a focus group. This is a group interview facilitated by a researcher and that focuses on a specific subject. It will consist of four members of healthcare staff from the unit, who have been selected as they have worked on the unit during the implementation of the arts activities. The interview will focus on experiences of these activities and how they have affected the working environment. No questions will be directed at any individual but will be directed at the group as a collective. You can choose whether or not respond throughout the interview and are not required to respond to any questions you do not wish to answer.

The focus group will be organised at a place and time that is convenient for all participants. Before the focus group takes place we will ask you to fill in a consent form stating that you agree to take part.

What are the possible benefits of taking part?

We cannot promise that this study will help you directly; however the results of the study will inform future research and service development that will aim to improve care provided to patients with end-stage kidney disease receiving haemodialysis in a way that will also improve the working environment for healthcare staff.

Important information

What will happen if I don't want to carry on with the study?

Involvement in the study is completely voluntary and you can decide to stop at any point. If you leave during the study we will not use the data that we have collected from you. You do not need to provide a reason for leaving the study.

How will the researchers keep my information confidential?

Any confidential audio or written information will be stored in locked filing cabinets, in a locked office, at Queen's University and will be destroyed after five years. All digital information will be transferred and stored on secure servers at Queen's University Belfast and will be password protected, therefore only the researchers (Claire Carswell, Dr Helen Noble, Dr Joanne Reid and Dr Ian Walsh) will have access to recordings of the interviews. Any identifiable information will be removed. If you have provided information that causes the researcher to be concerned about malpractice the researcher will be obliged to contact the line manager of the healthcare professional involved.

What will happen to the results of the research?

The results of this study will be published in peer-reviewed journals, presented at research conferences and will form a final PhD thesis. If you are interested we can provide you with a summary of results once data analysis has finished, and you can contact the research team if you would like a copy of any publications. The hope is that these results will inform a larger study and influence policy and practice.

Who funding and carrying out this research?

This study is part of a PhD project funded by the Department for the Economy (DfE). It is being carried out by Claire Carswell, a registered mental health nurse at Queen’s University Belfast. Her supervision team includes Dr Helen Noble, Professor Joanne Reid and Dr Ian Walsh

Who has reviewed the study?

This research has been reviewed by an independent Research Ethics Committee that is responsible for protecting the rights and safety of research participants. This study has been given a favourable opinion by the Office of Research Ethics Committees for Northern Ireland.

Who do I contact for further information?

If you have any questions or would like further information please feel free to contact:

Claire Carswell	School of Nursing and Midwifery
Telephone: 028 9097 5766	Queen's University Belfast
Email: ccarswell02@qub.ac.uk	
Dr Helen Noble	Medical Biology Centre
Telephone: 028 9097 2472	97 Lisburn Road
Email: helen.noble@qub.ac.uk	Belfast BT9 7BL
Professor Joanne Reid	
Telephone: 028 9097 2459	
Email: j.reid@qub.ac.uk	
Dr Ian Walsh	
Telephone: 028 9097 8983	
Email: i.walsh@qub.ac.uk	

Complaints procedure

If you have any complaints about the research or a member of the research team you have the right to complain. If you don’t wish to discuss your complaint with a member of the research team or your own healthcare team, please contact:

The Complaints Department
Bush House
Bush Road
Antrim
BT41 2QB
Tel: 0289442655
E-mail: user.feedback@northerntrust.hscni.net

Appendix 6: Participant consent form – Healthcare staff Phase 3



HCP Consent form – Process evaluation – Focus group

Study Title: Developing an arts-based intervention in patients with end-stage kidney disease receiving haemodialysis

Name of Researcher: Claire Carswell

		Please initial box
1	I confirm that I have read the information sheet dated 27.02.18 version 0.2 for the above study. I have had the opportunity to consider the information, ask questions, and had my questions answered fully.	
2	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.	
3	I understand that the study is being conducted as part of a PhD project from Queen's University Belfast and that any personal information will be held securely on the university premises and will be handled according to the Data Protection Act 2018	
4	I understand that this study is confidential but there are limits to this confidentiality. Revelations that are in clear breach of good medical practice may require confidentiality to be broken by the researchers.	
5	I understand the focus group will be tape recorded and there is a possibility of direct quotation being used in publications.	
6	I agree to take part in the focus group.	

Name of participant

Date

Signature

Researcher

Date

Signature

Anonymous ID code:

--

Appendix 7: Distress Protocol Patients

Distress Protocol - Patients

Rationale

Patients with end-stage kidney disease receiving haemodialysis are potentially vulnerable and experience lower health related quality of life compared to the general population, and are at a higher risk of developing mental health issues such as anxiety and depression. Discussions surrounding these issues may cause distress. Therefore it is important that researchers are sensitive to the person's distress and acts to minimise any potential exacerbation, and help identify agencies or services that can provide support.

Distress Protocol for Phase 2 and 3



Contact details for supportive services

Health Psychology Services Northern Health and Social Care Trust

The health psychology services provide a specialised renal counsellor. Please ask a member of your care team for a referral to this service

Clinical Health Psychology Service Holywell

Hospital Site, 60 Steeple Road, Antrim BT41 2RJ

Tel: 028 9441 3127

Email: psychology.bvh@northerntrust.hscni.net

Northern Ireland Kidney Patient Association

NIKPA, c/o Dialysis Unit,

Belfast City Hospital,

Lisburn Road,

Belfast BT9 7AB

email: info@nikpa.org

HMRC Charities Ref. No: NI00338

Northern Ireland Charity number: NIC104608

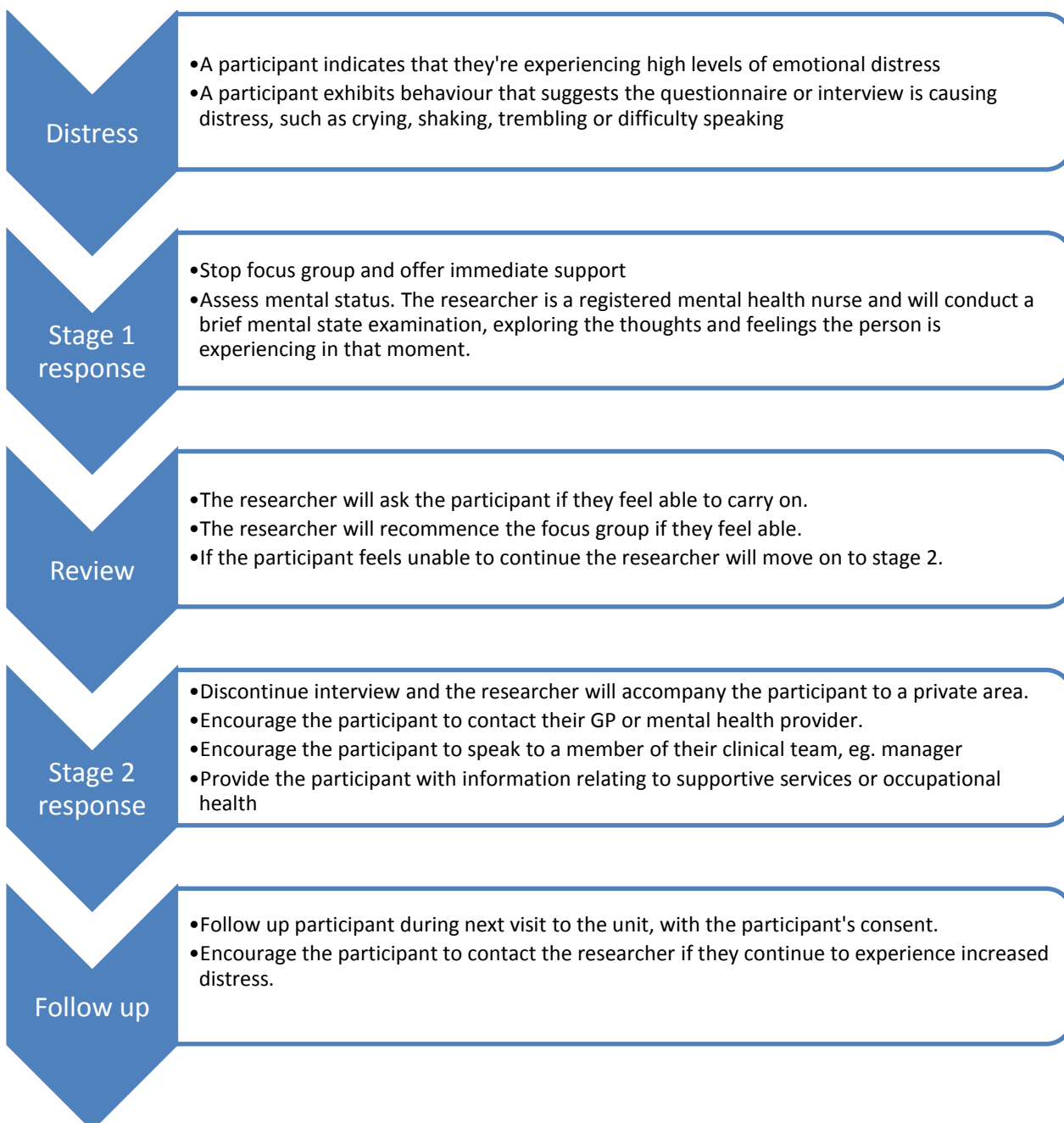
Appendix 8: Distress Protocol Healthcare staff

Distress Protocol – Healthcare Staff

Rationale

Patients with end-stage kidney disease experience difficult symptoms and have high rates of mortality. It is likely that during the course of this study healthcare staff working on the haemodialysis unit will experience the deterioration of the health of their patients, and potentially the death of patients. Discussions surrounding these issues may cause distress. Therefore it is important that researchers are sensitive to the person’s distress and acts to minimise any potential exacerbation, and help identify agencies or services that can provide support.

Distress Protocol for Phase 3



Contact details for supportive services

Occupational Health at Antrim Area Hospital

Occupational Health
Willow House
45 Bush Road
Antrim BT41 2RL
Tel: 028 9442 4403
Email: kevin.oconnor@northerntrust.hscni

Royal College of Nursing Counselling Services

To book a counselling session, call the RCN any time from 8.30am to 8.30pm, 365 days a year on 0345 772 6100.

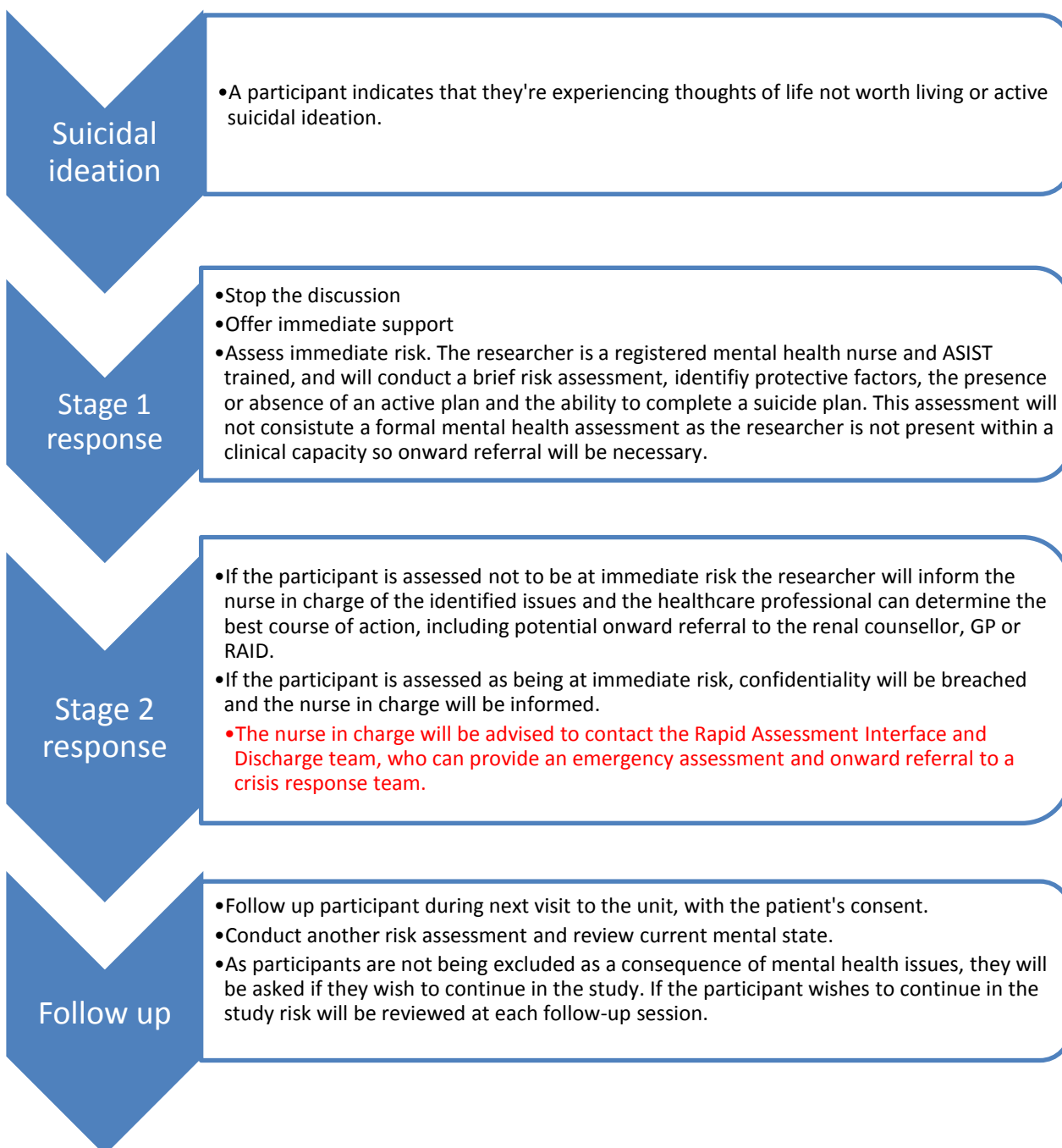
Appendix 9: Distress protocol – Suicide risk

Distress Protocol – Suicide Risk

Rationale

Patients with end-stage kidney disease are at high risk for developing mental health issues such as depression. One consequence could be an increased risk of suicide. The researcher will be administering the Hospital Anxiety and Depression scale during the project, and while this scale is not diagnostic of mental health issues and does not ask information on suicide or thoughts of life not worth living, the questionnaire may prompt patients to spontaneously disclose thoughts of suicide. Therefore it is important that researchers respond appropriately to reduce risk of harm.

Distress Protocol for suicide risk



The input from healthcare professionals to the distress protocol is an important consideration. Even though the potential for a spontaneous disclosure of suicide or harm is low, a risk assessment will be taken by the researcher who is a trained Mental Health nurse. The reason for the referral through the direct care team is procedural and reflects the standard process within the HSC. The researcher as an experienced mental healthcare professional will be able to advise the care team but feels it would be inappropriate to operate outside of the standard practices on site. The Sponsor has also requested that the researcher clearly separates their research and clinical roles.

Contact details for supportive services

Health Psychology Services Northern Health and Social Care Trust

The health psychology services provide a specialised renal counsellor. Please ask a member of your care team for a referral to this service

Clinical Health Psychology Service Holywell

Hospital Site, 60 Steeple Road, Antrim BT41 2RJ

Tel: 028 9441 3127

Email: psychology.bvh@northerntrust.hscni.net

Northern Ireland Kidney Patient Association

NIKPA, c/o Dialysis Unit,

Belfast City Hospital,

Lisburn Road,

Belfast BT9 7AB

email: info@nikpa.org

HMRC Charities Ref. No: NI00338

Northern Ireland Charity number: NIC104608

Renal Patient Support Group

The Renal Support Group meets on the second Monday every other month at All Saints Parish Centre in Ballymena from 11am – 12.30pm.

Lifeline

Telephone: 0808 808 8000

Textphone: 18001 0808 808 8000

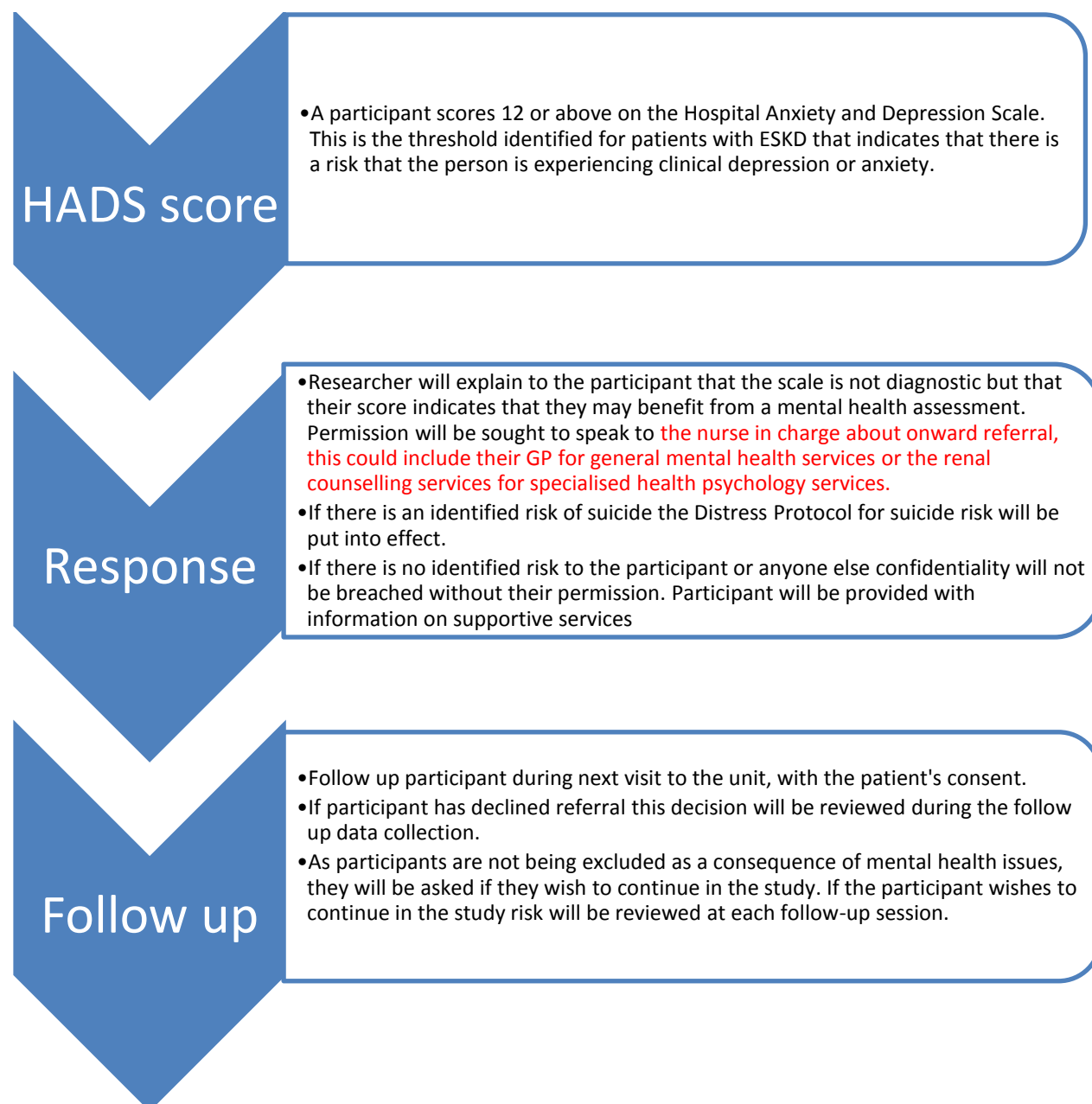
Appendix 10: Distress Protocol - HADS

Distress Protocol – HADS

Rationale

Patients with end-stage kidney disease are at high risk for developing mental health issues such as depression and anxiety. The researcher will be administering the Hospital Anxiety and Depression scale during the project, and while this scale is not diagnostic of mental health issues it can be used as a screening tool to identify high risk of depression and anxiety. Therefore it is important that the researcher identifies patients who at an increased risk so they can be properly assessed.

Distress Protocol for high risk of depression or anxiety



Contact details for supportive services

Health Psychology Services Northern Health and Social Care Trust

The health psychology services provide a specialised renal counsellor. Please ask a member of your care team for a referral to this service

Clinical Health Psychology Service Holywell

Hospital Site, 60 Steeple Road, Antrim BT41 2RJ

Tel: 028 9441 3127

Email: psychology.bvh@northerntrust.hscni.net

Northern Ireland Kidney Patient Association

NIKPA, c/o Dialysis Unit,

Belfast City Hospital,

Lisburn Road,

Belfast BT9 7AB

email: info@nikpa.org

HMRC Charities Ref. No: NI00338

Northern Ireland Charity number: NIC104608

Renal Patient Support Group

The Renal Support Group meets on the second Monday every other month at All Saints Parish Centre in Ballymena from 11am – 12.30pm.