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P241 -Recruitment and retention of participants to a pilot cluster randomised trial of an arts-based intervention for patients with end-stage kidney disease whilst receiving haemodialysis.

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Background

Many patients with end-stage kidney disease (ESKD) require haemodialysis, a treatment that impacts profoundly on quality of life. Arts-based interventions can potentially improve quality of life, however there is a lack of evidence assessing their impact on patients receiving haemodialysis and no randomised controlled trials (RCTs) of complex arts-based interventions. Recruitment and attrition in RCTs involving patients with ESKD is an recognised issue; therefore it is necessary to assess the feasibility of conducting an RCT of a complex arts-based intervention for patients with ESKD receiving haemodialysis prior to a definitive trial.

Aims

To evaluate the feasibility of recruitment and retention of participants to a cluster randomised controlled trial of an arts-based intervention for patients with ESKD whilst receiving haemodialysis.

Progression Criteria

A target sample size of 30 was identified as recommended by the National Institute for Health Research (NIHR) for parameter estimation within an RCT. In the present study recruitment of 75–100% of the target sample from a single site would result in progression to a definitive RCT. More than 20% attrition rate from the recruited sample would result in revision of the protocol prior to progression to a full trial.

Methods

Recruitment took place in a single haemodialysis unit in Northern Ireland. nursing staff acted as gatekeepers and screened patients for eligibility, whilst the researcher obtained written informed consent. Information on eligibility and reasons for non-participation were captured during the recruitment process. Clinical outcome measures collected included the Kidney Disease Quality of Life - SF36, the Hospital Anxiety and Depression Scale, and the EQ-5D-5L. Outcome measures were collected at baseline, post intervention, and at six weeks and 3 months follow up. Reasons for withdrawal were collected throughout the study.

Results

122 patients were screened for inclusion in the study and 94 were deemed eligible for participation. A total of 24 participants were recruited into the pilot cluster randomised controlled trial. The most common reasons for non-participation were a lack of interest in the arts (n=29) or anxiety over artistic ability (n=11). 80% of the target sample size was reached prior to randomisation. One participant withdrew from the study prior to post-intervention data collection, rendering the total attrition rate at 3 months as 12.5% (n=3). One participant died during the study, while two participants withdrew due to a decline in their physical health.

Conclusions

Recruitment and retention of participants to a cluster randomised controlled trial of an arts-based intervention for patients receiving haemodialysis is feasible. Normalisation of art on dialysis, for example by

providing examples of previously completed work, could potentially help improve recruitment and participation in a definitive trial by promoting interest in art and reducing anxiety. The total attrition rate was low and 95.8% of participants completed follow up at 6 weeks. Reasons for withdrawal were unrelated to the intervention or methodology. Future studies should be mindful of the changeable health of this population during recruitment to ensure adequate statistical power is maintained during follow up.