Statistical analysis plan for the feasibility and acceptability trial of the *Living Well with Haemodialysis* programme

Feasibility

Feasibility was assessed by recording recruitment, retention, weekly engagement, use of activities and adverse events. Positive feasibility was defined as: 1) recruiting at least 10 participants and recruiting 75% of those eligible over 3 months; 2) at least 80% retention; 3) at least 75% of participants engaged each week and using each activity; 4) no serious adverse events.

Acceptability

Acceptability was assessed by weekly and post-intervention feedback. Each week, participants rated how realistic the story was, how useful the explainer films were, and how useful that week's content would be to someone new to dialysis (5-point scales: 'not at all', 'slightly', 'moderately', 'very', 'extremely'). Post-intervention, participants indicated how often they used each of the activities and rated agreement with statements about the programme (5-point scales: 'strongly disagree' to 'strongly agree'). They also indicated how likely they would be to use the programme again and recommend it to people starting dialysis (5-point scales: 'definitely not' to 'definitely would'). Positive acceptability was defined as positive evaluations ('very' or 'extremely', and 'agree' or 'strongly agree') by at least 75% of participants.

Participants also indicated how they felt about completing the programme without a professional to talk to, and, having completed the programme, how likely they would be to look for psychological support. Three free-text questions asked: 'what were the best things about the programme?', 'how could it be improved?', and 'any other comments about the programme or how it affected you?'. Post-programme Interviews were recorded and the verbatim transcripts were analysed using descriptive thematic analysis (Braun & Clark, 2006).

Potential outcome measures

At pre-intervention and follow-up, participants completed the Kidney Disease Quality of Life Short Form (KDQOLSF) (Hays et al., 1997), the Acceptance and Action Scale, which measures psychological flexibility (AAS; Bond et al., 2011), and the Acceptance of Illness Scale (AIS; Felton et al., 1984). The KDQOLSF is a widely used condition-specific outcome measure, and the AAS and AIS measure psychological processes relevant to ACT. Feasibility and acceptability of outcome measures was defined as completion of scales with less than 10% missing data and indications they were viable before-and-after measures of change. Changes from pre-intervention to follow-up were tested with Wilcoxon signed-rank tests.

Rationale for targets for feasibility and acceptability

The recruitment target was low to enable the researchers to communicate with participants individually. Other targets were based on previous trials of behavioural interventions for

people receiving dialysis and ACT interventions for long-term conditions, plus CONSORT guideline examples. A feasibility trial of an intervention for people receiving haemodialysis had targets of 75% recruitment and 80% retention (Carswell et al., 2020). In a trial of ACT for chronic fatigue, 80% completed the programme and 66.7% reported they would recommend it (Jonsjö et al., 2019). CONSORT guideline examples had targets of 70% for participating in workshops, 65% for mean satisfaction with workshops, and less than 10% for missing questionnaire data (Eldridge et al., 2016).

References

- Bond, F.W., Hayes, S.C., Baer, R.A., Carpenter, K.M., Guenole, N., Orcutt, H.K., Waltz, T., & Zettle, R.D. (2011). Preliminary psychometric properties of the Acceptance and Action Questionnaire–II: A revised measure of psychological inflexibility and experiential avoidance. *Behavior Therapy*, 42, 676-688.
- Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77-101.
- Carswell, C., Reid, J., Walsh, I., Johnston, W., McAneney, H., Mullan, R., Lee, J.B., Nelson, H., Matthews, M., Weatherup, E., & Spencer, A. (2020). A mixed-methods feasibility study of an arts-based intervention for patients receiving maintenance haemodialysis. *BMC Nephrology*, *21*(1), 1-16.
 - https://bmcnephrol.biomedcentral.com/articles/10.1186/s12882-020-02162-4
- Eldridge, S. M., Chan, C. L., Campbell, M. J., Bond, C. M., Hopewell, S., Thabane, L., & Lancaster, G. A. (2016). CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *bmj*, 355. <u>https://www.bmj.com/content/355/bmj.i5239.full</u>
- Felton, B. J., Revenson, T. A., & Hinrichsen, G. A. (1984). Stress and coping in the explanation of psychological adjustment among chronically ill adults. *Social Science and Medicine*, 18, 889–898. <u>https://doi.org/10.1016/0277-9536(84)90158-8</u>
- Hays, R.D., Kallich, J.D., Mapes, D.L., Coons, S.J., Amin, N., Carter, W.B., & Kamberg, C. (1997). Kidney Disease Quality of Life short form (KDQOL-SF tm), version 1.3. A Manual for Use and Scoring. Santa Monica CA: RAND.
- Jonsjö, M. A., Wicksell, R. K., Holmström, L., Andreasson, A., & Olsson, G. L. (2019). Acceptance & commitment therapy for ME/CFS (chronic fatigue syndrome)–a feasibility study. *Journal of Contextual Behavioral Science*, 12, 89-97. <u>https://doi.org/10.1016/j.jcbs.2019.02.008</u>

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