

Global Trials Focus

April 2022

The ISN-ACT (Advancing Clinical Trials) team presents this monthly round up of randomized trials in nephrology. Trials are selected not just for impact, but also to showcase the diversity of research produced by the global nephrology community. Each trial is reviewed in context and has a risk of bias assessment. We hope to drive improvement in trial quality and promote greater engagement in trial activity.

Key to risk of bias assessment

-  Random sequence generation
-  Allocation concealment
-  Blinding of participants/personnel
-  Blinding of outcome assessment
-  Complete outcome data
-  Complete outcome reporting
-  No other sources of bias

High risk 
Uncertain risk / not stated 
Low risk 

Do you agree with our trial of the month? Tell us what you think!

@ISNeducation 

Want to run your own trial?
ISN-ACT Clinical Trials Toolkit
www.theisn.org/isn-act-toolkit

Would you like to write your own reviews?
Join the GTF team.

Contact us at research@theisn.org

ISN Academy: [Hemodialysis](#)

No easy fix: challenges in addressing depressive symptoms in individuals on haemodialysis

Internet-based treatment for depressive symptoms in hemodialysis patients: A cluster randomized controlled trial

[Nadort et al. Gen. Hosp. Psychiatry. 2022](#)



Reviewed by A Gallagher

Summary: One hundred and ninety individuals on chronic in-centre haemodialysis with depressive symptoms were cluster-randomized to either an internet-based self-help therapy or usual care. The intervention therapy was a problem-solving therapy that forms part of cognitive behavioural therapy. Screening for inclusion and assessment for the primary outcome was done using the Beck Depression Inventory – second edition (BDI-II), the mean of depression severity scale was 19 out of a possible 63 in both groups (with a score of 14-19 equating to mild depression) . Only 67% participants completed the study and just over half of the intervention group completed at least three of the 10 intervention modules (54%). Those lost to follow up were more likely to be of non-Dutch origin, married or on the wait list for a renal transplant. The most common reasons reported for not completing the intervention were health problems, lack of motivation or death. Also, 18% who started the therapy needed help with tablet computer usage and 45% also needed help with filling out the exercises. There was no significant difference in the depression scores found (mean difference -0.1, 95% CI -3.0 to 2.7, p=0.94) for either the intention to treat or per protocol analyses.

Comment: Mood disorders such as depression are well recognised comorbidities for individuals with chronic diseases with high treatment and symptom burdens such as those on chronic haemodialysis. Despite this, there is little evidence for what constitutes an effective therapy for these patients. Some early non-randomised studies into the use of cognitive behavioural therapies (CBT) has shown some promise in this population, with varied levels of efficacy depending on method of delivery. Disappointingly, this Dutch study was unable to demonstrate a benefit for a web-based self-directed intervention using CBT strategies. This may be related to difficulties with powering and lost to follow up but, given the challenges in achieving acceptance and uptake of this tool, it is likely that alternative strategies that are more “user friendly” to a dialysis cohort are required rather than further trials testing this intervention.

Edited by A Gallagher, DV O’Hara, M Provenzano, and A Zykova