

Global Trials Focus

October 2020

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.

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 Gallagher A, O'Hara DV, Smyth B 编辑

Text translated by Dr Lili Zhou in Mandarin

ISN-ACT (临床试验前沿) 团队每月提供肾脏病学的随机临床试验集锦。针对这些试验的选择不仅考虑到了它们的影响力, 同时也为了要展示全球肾脏病学界的研究多样性。每项试验都被赋予了短评并评估了偏倚风险。我们希望借此推动并提高临床试验的质量, 并促进更多的人参与临床试验的研究活动。

Key to risk of bias assessment

- (R) Random sequence generation
- (A) Allocation concealment
- (BP) Blinding of participants/personnel
- (BO) Blinding of outcome assessment
- (CD) Complete outcome data
- (CR) Complete outcome reporting
- (B) 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!

@ISNkidneycare 

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

偏倚风险评估指标

- (R) 随机序列产生
- (A) 分配隐藏
- (BP) 受试者和研究人员的盲法
- (BO) 结果评价的盲法
- (CD) 完整的结果数据
- (CR) 完整的结果报告
- (B) 无其他偏倚

高风险 ●
 风险不明/未描述 ●
 低风险 ●

Contents

内容

LOL-HD study: Laughter therapy may reduce depressive symptoms in hemodialysis patients.....	1
LOL-HD 研究: 笑声疗法可以减轻血液透析患者的抑郁症状.....	1

For this edition, the trial of the month will be translated into multiple languages and the remaining trials are discussed in English.

在这一期中, 月度临床试验将被翻译成多种语言, 其余的试验用英语讨论。

LOL-HD study: Laughter therapy may reduce depressive symptoms in hemodialysis patients

The effects of laughter therapy on depression symptoms in patients undergoing center hemodialysis: A pragmatic randomized controlled trial

LOL-HD研究：笑声疗法可以减轻血液透析患者的抑郁症状

笑声疗法对血液透析中心患者抑郁症状的影响：一项实用的随机对照试验

[Bennet et al. Hemodial Int. 2020 Aug 25.](#)

[Bennet等。Hemodial Int杂志。2020年8月25日](#)



Reviewed by Smyth B

Smyth B 评议

About the study In this cluster-randomized trial, 10 dialysis centers were randomised to receive weekly laughter therapy sessions for eight weeks or usual care. Qualified laughter therapists facilitated 30-minute intentional laughter exercises, which also included breathing and stretching exercises, and laughter meditation. Sessions were performed around 1 hour after patients had commenced dialysis. The primary outcome of depressive symptoms was measured by the depression subscale of the PHQ-4 survey.

研究概述 在这项集群随机试验中，10个透析中心被随机分配到接受连续8周、每周接受笑声治疗或常规护理的组别中。具备执业资格的笑声治疗师们辅助患者进行30分钟的有意笑声练习，其中包括呼吸和伸展练习，以及笑声冥想。笑声治疗在患者开始透析后1小时左右进行。通过PHQ-4抑郁调查量表来衡量抑郁症状的主要转归。

Results Compared to the control group, the laughter group showed a significant reduction in the number of participants reporting depression symptoms between study start and end (11 [17%] to 5 [8%] vs. 17 [22%] to 16 [20%]; $P=0.04$). There was no significant difference in the likelihood of depression between the two groups (odds ratio 0.37, 95% CI 0.13-1.01; $P=0.05$). There were no significant changes in measures of anxiety or well-being and no adverse events.

结果与对照组相比，在笑声治疗组中，在研究开始和结束期间报告具有抑郁症状的受试者数量显著减少（11[17%]到5[8%]对比17[22%]到16[20%]； $P=0.04$ ）。两组患者患抑郁症的概率无显著性差异（优势比0.37，95%CI 0.13-1.01； $P=0.05$ ）。焦虑和幸福感的测量没有显著变化，也没有不良事件。

Comment This interesting study provides some evidence to suggest that group laughter therapy is useful for hemodialysis patients. Questions remain given the high number of participants who did not complete surveys, especially the number who completed pre-study but not post-study surveys (81/153 [53%] in the laughter group and 40/119 [34%] in the control group). The authors themselves noted that introducing this group activity was challenging and that, despite measures to encourage acceptance, around 20% of patients remained reluctant to participate. Nevertheless, laughter therapy is inexpensive and could be considered as a means to improve the experience of patients on hemodialysis.

述评 这项有趣的研究提供了一些证据，表明了集体笑声疗法对于血液透析患者是有益的。由于没有完成调查的受试者人数很多，尤其是完成了前期研究而没有完成后续研究调查的人数较多（笑组81/153[53%]和对照组40/119[34%]），问题仍然存在。作者们自己也注意到，引入这种团体活动具有挑战性，尽管采取了鼓励接受的措施，但仍有约20%的患者不愿意参与。然而，笑声疗法是廉价的，可以被认为是一种改善血液透析患者体验的方法。