

A Brief Mindful Drinking/Eating Intervention for Hemodialysis Patients with Fluid Restrictions

NCT #04016311

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Study Protocol:

1. Randomize into intervention or control group by cohort days (M-W-F or T-TH-Sa).
2. Dialysis staff will identify patients that meet inclusion and exclusion criteria for the targeted dialysis session (sessions in which one of the researchers is available to attend) and ask if they are interested in talking to a researcher about participating in a research study.
3. Research staff will talk to interested patients about the study as part of the consent process and obtain written, informed consent.
4. All participants will fill out questionnaires (e.g., Background Information, Kidney Disease Quality of Life, Renal Adherence Behavior Questionnaire, Mindful Eating Questionnaire).

For participants in the intervention group only (items 5-15):

5. Researcher will introduce the idea about mindful drinking and eating activities and guide the participant through mindful eating of frozen grapes and mindful drinking of water.
6. Researcher will discuss the experience with the participant.
7. Researcher will provide directions for practicing mindful drinking/eating at home and review the activity checklist.
8. During week 2, the researcher will guide the participant through mindful eating of frozen blueberries and mindful drinking with cold juice, followed by a discussion of the experience.
9. The weekly activity checklist will be collected, and researcher and participant will discuss how the mindful drinking/eating practice went at home along with problem solving any barriers that occurred.
10. During week 3, the researcher will guide the participant through mindful eating of hard candy and mindful drinking of a hot liquid, followed by discussion of the experience.
11. The weekly activity checklist will be collected, and the researcher and participant will discuss how the mindful drinking/eating practice at home went along with problem solving any barriers that occurred.
12. During week 4, the researcher will guide the participant through mindful eating of a popsicle and mindful drinking of water with lemon, followed by discussion of the experience.
13. The weekly activity checklist will be collected, and the researcher and participant will discuss: how the mindful drinking/eating practice went at home, how to handle any barriers that occurred, and goals for continuing mindful eating/drinking into the future.
14. At week 4, all participants will fill out post-intervention questionnaires (e.g., Exit Questionnaire, Kidney Disease Quality of Life, Renal Adherence Behavior Questionnaire, Mindful Eating Questionnaire).
15. The researcher will ask for feedback from those in the intervention group about the interventions sessions and home practice using an Exit interview guide. Answers will be recorded in writing.

16. The researcher receive data from participants' electronic health record (e.g., pre- and post-intervention interdialytic weight gain) from dialysis staff.

17. Wait list control group receives same intervention described in steps 5-15 at the completion of the intervention. (OPTIONAL)

Statistical Analysis Plan: This is a small, exploratory pilot study. Data will be analyzed using descriptive statistics to describe the sample and the measures. Differences between pre- and post- intervention measures will be examined using paired t-tests for each arm of the study.