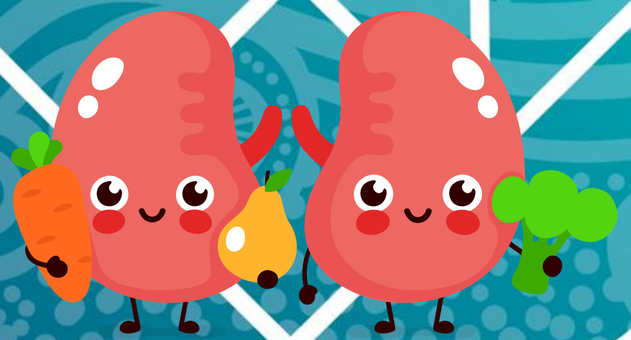
Kidney-Healthy Eating and Lifestyle Program (Kidney-HELP): a randomized feasibility trial

(ACTRN12624000057583)



Erynn McAuley, Dr Lynda Ross, Assoc Prof Mary Hannon-Jones, Dr Louise Purtell, Dr Mala McHale, Dr Sharad Ratanjee & Assoc Prof Helen MacLaughlin

1. School of Exercise and Nutrition Sciences, Queensland University of Technology, Kelvin Grove, Queensland, Australia
2. Nutrition & Dietetics, Logan Hospital, Meadowbrook, Queensland, Australia
3. Nutrition Research Collaboration, Royal Brisbane and Women's Hospital, Herston, Queensland, Australia
4. Research Development Unit, Royal Brisbane and Women's Hospital, Herston, Queensland, Australia
5. Psychology Department, Royal Brisbane and Women's Hospital, Herston, Queensland, Australia
6. Kidney Health Service, Royal Brisbane and Women's Hospital, Herston, Queensland, Australia

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QUT Queensland University of Technology

Metro North Health | Queensland Government

Background

- Adherence to high-quality dietary patterns may reduce risk of disease progression[1-7] and all-cause mortality[3,6,8-10] in adults with CKD. However, we need RCTs to confirm these outcomes.

- Diet quality refers to a healthy and balanced diet that is characterized by a high intake of fruits, vegetables and wholegrains and low intake of saturated fat, sodium and refined sugar.[11]

- Adults with CKD have poor to moderate diet quality.[12-15]

- Increased self-efficacy has been associated with increased diet quality in adults with CKD[15] and is a powerful predictor of behaviour change.[16]

- Self-efficacy refers to a person's belief and confidence in their ability to perform specific tasks.[17]

1. Tirosh et al. 2013; 2. Banerjee et al. 2019; 3. Hu et al. 2020; 4. Díaz-López et al. 2021; 5. Podadera-Herreros et al. 2022; 6. Amir et al. 2023; 7. Martínez-Montoro et al. 2025; 8. Kelly et al. 2017; 9. Thompson et al. 2024; 10. Zhu et al. 2024, 11. Alkerwi et al. 2014; 11. Fernandes et al. 2018; Heindel et al. 2020; 13. Bin Zarah et al .2024; 14. Hammer et al. 2024; 15. McAuley et al. 2024 16. AbuSabha et al. 1997; 17. Bundara, 1997

Aim

To evaluate the feasibility and acceptability of a Group and a Self-paced Kidney-HELP, a self-efficacy based dietary intervention aimed at improving diet quality in adults with CKD.

Methods

12-week, parallel-group. randomised feasibility trial with a mixed-methods design

Participants

Eligible participants are adults aged 18-75 years with CKD stages G3-G4 under the care of a Metro North Nephrologist and able to provide informed consent
Exclusion criteria:

- Non-English speaking or unable to read/write in English
- Pregnancy, breastfeeding or planning pregnancy in the next 6 months
- Cognitive impairment that would prevent participation
- Serious mental illness
- Malnourished (SGA B or C)
- Receiving palliative or supportive care, or
- Currently taking part in another diet-related clinical trial

Recruitment, Randomisation & Interventions

Screening & Recruitment

- Nephrology clinic lists screened for eligibility
- Eligibility confirmed by SMOs
- Eligible patients were mailed PICF and then contacted by phone 1-2 weeks after their appointment if no response

Randomisation

Participants who provided informed consent were block randomised (1:1) to Group Kidney-HELP or Self-Paced Kidney-HELP

Group Kidney-HELP

- 7-week existing lifestyle program for patients with chronic disease (face-to-face or telehealth) by psychologist and dietitian
- Topics: Goal setting, Self-monitoring, Dietary recommendations, Planning for better health, Mindful eating, Staying on track
- 2 Kidney Specific Sessions (face-to-face or telehealth): recipe modification and eating out, salt and your kidneys
- Received Kidney-HELP Workbook

Self-paced Kidney-HELP

- Receive Kidney-HELP Workbook (7-chapters)
- Instructed to complete 1 chapter per week
- Received weekly survey to assess program adherence

Dietary Recommendations:
Australian Dietary Guidelines and the Australian Heart Foundation Dietary Recommendations

Outcomes

Primary outcomes

- ***Feasibility***
  - **Recruitment:** ≥35% of all eligible and contacted patients are recruited
  - **Retention:** ≥80% of recruited participants maintained at 12 weeks
  - **Program adherence:**
    - ≥50% attendance to Kidney-HELP Sessions (Group), or
    - ≥50% of Kidney-HELP workbook read and completed (Self-paced)
- ***Acceptability*:** semi-structured interviews (n=14)

Secondary outcomes

- Dietary adherence (Healthy Eating Screener)
- Diet quality (3 x 24-hour dietary recalls, Healthy Eating Index for Australians - 2013)
- Dietary self-efficacy (Nutrition Self-efficacy Scale)
- Disease management self-efficacy (Self-efficacy for Managing Chronic Disease - 6-item scale)
- Health related quality of life (5-level EQ-5D)

Results

Participant characteristics (n=48)	Kidney-HELP group (n=23)	Kidney-HELP Self-paced (n=25)
	Mean ± SD, Median [IQR] or n (%)	
Age, years	62.3 ± 8.7	57.6 ± 11.7
Males	11 (47.8)	8 (32)
eGFR, mL/min/1.73m^2	45.0 [20]	43.1 ± 10.2
Body mass index, kg/m^2	32.8 ± 8.0	33.3 ± 7.9
Comorbidities		
Hyperlipidaemia	11 (47.8)	8 (32.0)
Hypertension	18 (78.3)	18 (78.3)
Cardiovascular disease	12 (52.2)	5 (20.0)
Type 2 Diabetes	13 (56.5)	6 (24.0)
Type 1 Diabetes	0	1 (4.0)
Education		
Did not complete high school	9 (39.1)	6 (24.0)
Completed high school / vocational educational	6 (26.2)	12 (48.0)
Completed higher education	8 (34.7)	6 (28.0)
Country of birth, n(%)		
Australia	16 (69.6)	17 (68.0)
New Zealand and Pacific Islands	4 (17.4)	4 (16.0)
Other	3 (13.0)	4 (16.0)

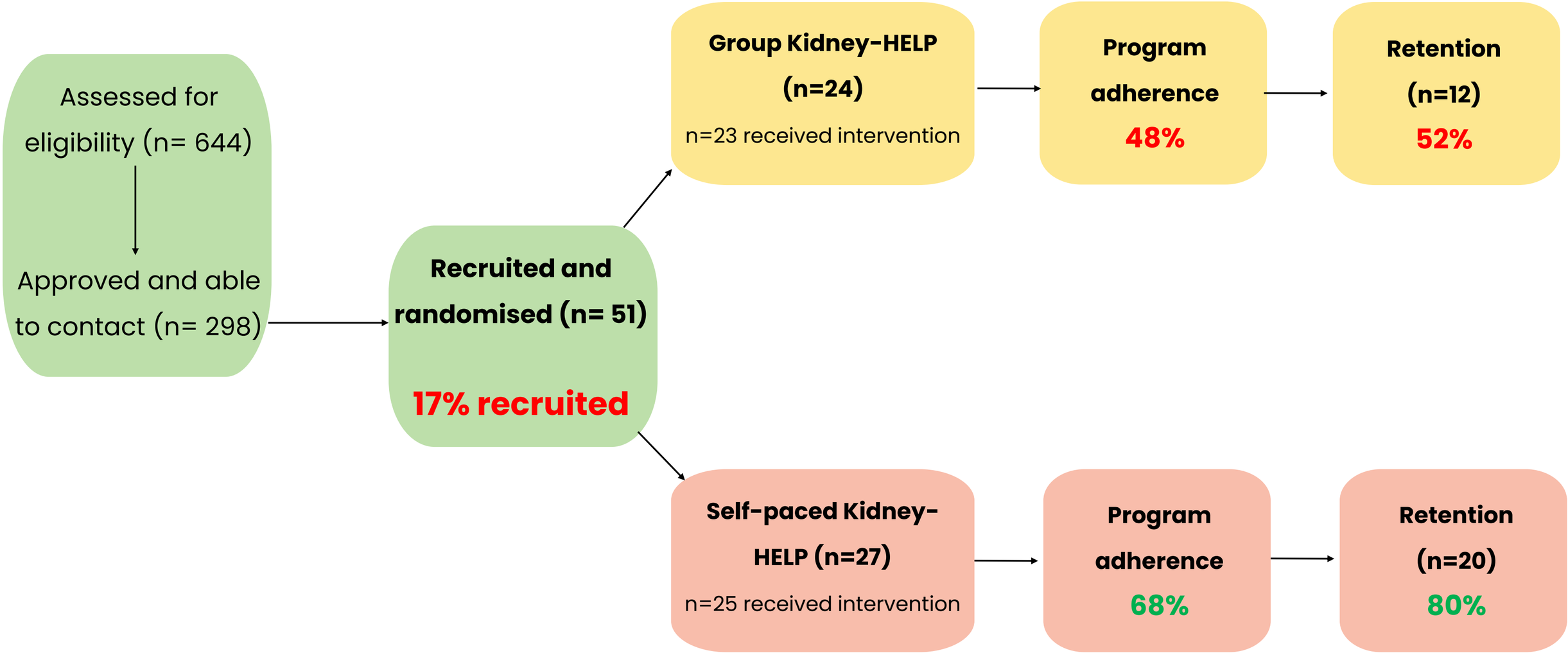
Results

Feasibility Targets

Recruitment ≥35%

Program adherence ≥50%

Retention ≥80%



Results

Attitudes towards Kidney-HELP

- **Positive attitude:** “It was really, really, really practical… You know, we had all the information there. It was nice and simple and clear and easy to read… it was just what it needed to be for the course” (G16).

Acceptabilty

Barriers to attendance, adherence and dietary changes

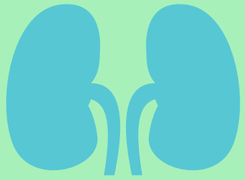
- **Life gets busy:** “I mean… that was my issue in the end, you know, if it's not work and it's not during… school hours and if it's not on a Friday, it's just finding the right time to be able to attend” (G16).
- **Feeling overwhelmed by the workbook**: “It was quite good when you break it down, like when I first got, I think when we started, I went, Oh my God” (G13).
- **Financial struggles**
- **Difficulties with problem solving and concerns with literacy levels**

Results

Kidney-HELP is easy to understand and accessible

- **The workbook is *a little gold mine* that can be improved even further:** " if they've got the book, those worksheets can be digitally available, so that you can just go online and fill them out" (S2).
- **Telehealth group sessions were preferred**
- **Enjoyed completing the program self-paced**: "I'll give you an example. I don't think I would have made it through the program if I'd had to go down to a group" (S32).

Acceptabilty



Developing self-efficacy

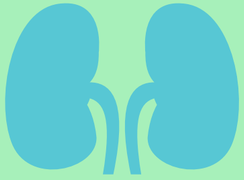
- **Motivated to improve kidneys and health:** "My main motivation was to, you see, my kidneys... just trying to keep them as healthy as possible." (G22).
- **Staying accountable and increasing awareness through self-monitoring**: "It's being more aware of how much unprocessed or processed food I was eating." (S51).
- **Valuing support from facilitators, peers and carers:** "it was just nice to know that you're not alone" (G41).
- **Feeling confident and empowered to continue to change:** "If I want to eat a lot more healthier, then it is achievable... I can do it" (G41).
- **Problem solving and working around barriers**

Results

Acceptability

Importance of understanding dietary recommendations for CKD

- **Specific kidney nutrition information is essential**
- **Learning what a serve is, was a key takeaway:** “That sounds crazy, but a serving, to me was whatever gets put on your plate. Now I actually pick the servings and try and make the serving sizes correct ” (G13).
- **Eating mindfully and staying on track were important messages:** “remind me why to bother, why to not lose track if I'm either feeling a bit down, or just too much stress happening” (G54).
- **Participants want more practical resources and tips**

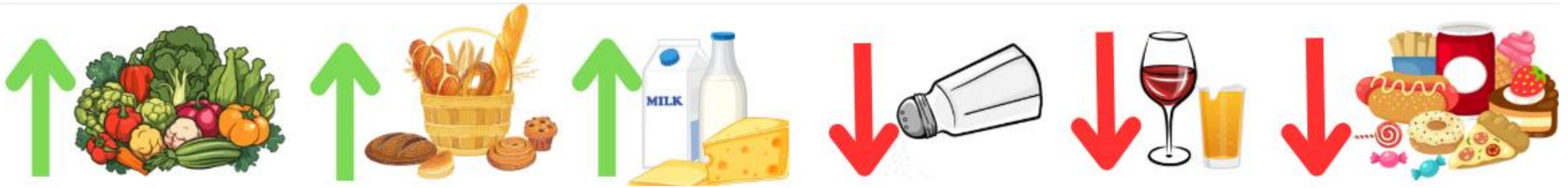


Perceived effectiveness of Kidney-HELP

- **Changes seen in kidneys and overall health:** “I went and saw her, Dr [nephrologist], and she said that... I don't need to come back. And I said, well... you know, I think this program that I'm doing with you has made all the difference, because it's making me eat healthier. I've lost weight... I feel better. Yeah, and a lot healthier” (S51)
- **Changes in eating, nutrition literacy and other health habits:**
  - “And that's where I was like, mate, I'm not having enough veggies. Yeah, I love my fruit, but I got to cut that back. And yeah, so it showed me what I should cut back and what I should add in.” (G13)
  - “I still haven't had a cigarette, but it also changed the way I ate. It was a lot of things.” (G37).

Results

Outcome	Kidney-HELP Group, n=12			Self-paced Kidney-HELP, n=20			Difference between groups at 12 weeks (95% CI)
	Baseline	12-weeks	Change	Baseline	12-weeks	Change	
Diet quality and dietary adherence							
Dietary adherence (HES, 0-14)	8.0 [2.0]	9.3 ± 3.0	**2.5 (0.1, 4.9)***	8.0 [2.5]	9.8 ± 2.5	**2.0 (0.7, 3.2)***	-0.4 (-2.6, 1.8)
Self-efficacy							
Dietary self-efficacy (NSES, 0-20)	16.0 [4.0]	18.0 [5.0]	1.6 (-0.1, 3.2)	15.0 [6.0]	19.0 [5.0]	**1.7 (0.1, 3.3)***	-0.3 (-2.2, 1.6)



There were no changes in diet quality, quality of life or self-efficacy for managing chronic disease

Self-paced Kidney-HELP met feasibility criteria : retention and adherence

The program overcame barriers of access and reduces barriers to program adherence, allowing participants flexibility in when and where they complete the program.

Both Group and Self-paced Kidney-HELP were acceptable:

- Participants were motivated to prevent disease progression and valued kidney-specific information as well as education on serving sizes and mindful eating.
- Self-monitoring strategies were key in creating accountability and developing participant's nutrition literacy.

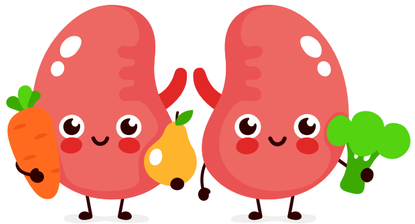
Kidney-HELP may lead to improvements in dietary self-efficacy, dietary adherence and diet quality.

Limitations: small sample size with short duration, self-reported program adherence and dietary data, didn't cater for lower literacy participants, participants had higher education levels and may not represent general population with CKD, group arm had higher rates of diabetes & CVD, participants who dropped out weren't interviewed

Learnings and future directions

Self-paced delivery method can be implemented with support: participants identified that support was key to the self-paced approach and suggested modifications to the workbook to improve the program.

Several adaptations should be considered:

- Adapt for adults with low health literacy
- Deliver program with different format options (print, digital, audio or combination) with short educational videos
- Offer additional weekly support and feedback by text message or telehealth
- Integrate peer support into the self-paced program
- Include more information specific to CKD

Future research is needed to demonstrate long-term adherence and establish the effects of healthy dietary patterns on patient-reported and clinical outcomes.