

Ten-Hour Time-Restricted Feeding Improves Post-Kidney Transplantation Dyslipidemia—a randomized controlled trial

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Ten-Hour Time-Restricted Feeding Improves Post-Kidney Transplantation Dyslipidemia: a randomized controlled trial

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Abstract:

Background: Atherosclerotic cardiovascular disease is a key cause of graft failure and death of kidney transplant recipients.

Objective: Time-restricted feeding (TRF) may be a potential way to help alleviate metabolic disorders in this population.

Methods: Twenty-four kidney transplant recipients who had habitual daily feeding windows of >10 hours were randomly assigned to two groups. After a 12-week period of TRF, anthropometric and metabolic parameters were compared between groups and analyzed for changes from baseline.

Results: In this randomized controlled trial, the change in cholesterol (δ cholesterol) was found to have a statistically substantial variance between groups ($P = 0.001$). Relative to the baseline, TRF was linked with significant reductions in triglycerides ($P = 0.003$) and total cholesterol ($P = 0.001$) levels.

Conclusions: TRF may be beneficial in improving post-transplant dyslipidemia in kidney transplant recipients.

Trial registration: The randomized controlled trial has been registered with the Chinese Clinical Trial Registry under the registration number ChiCTR2500098769. <https://www.chictr.org.cn/index.html> on 2025-03-13.

Keywords

kidney transplantation; dyslipidemia; time-restricted feeding; metabolic disease, circadian rhythms

1.Introduction

With the improvement in surgical techniques and the emergence of new immuno-suppressive agents, the long-term survival of the kidney transplant recipient has improved significantly. Consequently, atherosclerotic cardiovascular disease (ASCVD) has become a main cause of graft failure and recipient death [1, 2].

Kidney transplantation, considered the key standard treatment for end-stage renal disease, is often accompanied by post-operative metabolic disorders, such as hyperlipidemia, post-transplant diabetes mellitus and hypertension. Data show that post-transplant dyslipidemia is almost inevitable, as the incidence is as high as 80%, and post-transplant diabetes mellitus occurs in 10% to 20% of cumulative recipients [3, 4]. These metabolic conditions are determined high-risk factors for post-transplant cardio-vascular events [2].

Time-restricted feeding (TRF) is an evolving dietary pattern, which is designed to achieve weight control by restricting the timing of daily food intake to a specific time period and only consuming water/tea during the remaining time. Previous studies suggest that TRF may also have cardiometabolic benefits, including decreased fasting blood glucose, reduction in insulin resistance [5], and even lowered blood pressure with no effect on body weight [6, 7]. A limited number of studies have further indicated that TRF can affect

lipid metabolism. Of note, TRF, especially with a 10-hour feeding window, has seldom been linked to adverse effects in participants [7, 8], making it a safe and feasible dietary approach.

Therefore, TRF could be an ideal dietary approach for the enhancement of the post-transplant metabolic syndrome. To our knowledge, this regimen has not yet been tested in kidney transplant recipients. In this study, we hypothesize that 10-hour TRF can improve metabolic disturbances after kidney transplantation.

2.Methods

2.1.Participant recruitment

We recruited participants from the outpatient clinic of the Kidney Transplantation Department at Yiyang central hospital.They underwent blood sample collection and physical measurements (including BMI, body weight, and height) at the beginning and the end of the experiment. During the intervention period, they record their daily start and end times of food intake and report them to the data recorder.

2.2.Inclusion and exclusion criteria

Inclusion Criteria: Participants were considered eligible if they were 18-75 years old, >3 months post-transplantation, had serum creatinine (Cre) fluctuations of less than 20% over 3 consecutive follow-up tests and an eGFR >30 mL/min/1.73 m² .

Exclusion Criteria: Participants were excluded if they had acute or chronic viral hep-atitis, malignancy, severe liver dysfunction, current smoking, severe cerebrovascular or cardiovascular disease within six months before the randomization, severe gastrointestinal

disease or history of gastrointestinal surgery within twelve months before the randomization, active participation in a weight-loss program, or current/planned pregnancy.

2.3.Study design

Participant enrollment was completed from April to June 2025. Following the collection of three weeks of data regarding habitual feeding windows, baseline measurements were taken. TRF was defined as completion of all daily food intake within any 10-hour window with no restriction on energy intake and no intake of anything other than water or unsweetened tea outside this window. Based on whether or not participants followed a 10-hour feeding window for at least five days a week, they were separated into two groups: the TRF group and the long time feeding (LTF) group.

Participants in the LTF group were then randomized 1:1 by study staff who had no direct contact with participants. One subgroup followed a 10-hour TRF regimen (LTF→TRF), and the other group followed their normal dietary pattern (LTF→LTF, control). After 12 weeks, the primary outcome was the variance in body weight change from baseline between the two groups. Secondary outcomes were waist circumference, body mass index (BMI), hip circumference, metabolic risk factors (glycated hemoglobin A1c [HbA1c], lipid profiles, blood glucose, and blood pressure), renal graft function (Cre, blood urea nitrogen), and nutritional indicators (albumin). The study flow chart is presented in Figure 1. Independent investigator monitored the daily eating windows of the participants by WeChat. Because participants had to take calcineurin inhibitor (CNI) medications on an empty stomach at 8:00 AM and 8:00 PM, their meal times were relatively regular, which improves the accuracy of their reported eating times.

2.4.Detection method

89 Anthropometric Measurements: Height and body weight were measured with the help of a standard weighing scale, and hip and waist
90 circumferences were measured with the help of a tape measure. Moreover, BMI was determined as: $\text{body weight (kg)}/\text{height (m)}^2$.

91 Blood Sample Collection and Storage: Blood samples were taken at baseline and at the end of the study. Prior to collection,
92 participants were requested to adhere to a low-fat diet for 1-2 days and fast after 8:00 PM on the day before sampling. Fasting blood
93 samples were taken by a professional nurse at the kidney transplant outpatient clinic between 7:00 AM and 8:00 AM. Collected
94 samples were transported immediately to the clinical laboratory of the hospital for analysis.

95 Biochemical Assays: Biochemical parameters, such as complete blood count (CBC), kidney and liver function tests, urinalysis, and
96 glycated HbA1c were analyzed using standardized commercial assay kits.

97 Liver Function Tests: Alanine aminotransferase: Measured by alanine substrate method (Catalog No. GB000G). Aspartate
98 aminotransferase: Determined with the aspartate substrate method (Catalog No. CB010G). Total bile acids (TBA): Determined by
99 enzymatic cycling (Catalog No. GS061G). Total protein: Measured by the biuret method (Catalog No. GS0911G). Albumin (ALB):
100 Measured by the bromocresol green method (Catalog No. GS0921G). Total bilirubin (T BIL) and Direct bilirubin: Measured by the
101 vanadate oxidation method (Catalog Nos. GS9021G and GS9031G, respectively).

102 Kidney Function Tests: Urea (UREA): Urea is measured by urease glutamate dehydrogenase (Catalog No. GS9311S). Uric acid:
103 Tested by uricase method (Catalog No. GS321S). Cre: Measured by the sarcosine oxidase method (Catalog No. GS9301S).

104 CBC: Assay kit model: XE 5000. Hemoglobin (HB): Measured by spectrophotometry with hemolytic agent for the analysis of blood
105 cells (Batch No. A3005). White blood cell count: Flow cytometry SLS HB hemolytic agent red blood cell count (RBC): Using flow
106 cytometry with sheath fluid and HB staining solutions (Batch Nos. ZA3009 and A4001).
107 Urinalysis: Assay kit model, FU 3000. Urine analysis was done by dry chemistry or colorimetric methods. Dry chemistry was done
108 using dry chemical test strips (Batch No. 20230815) and the colorimetric method was done using urine laminar flow solution (Batch
109 No. 20231223). Urine sediment analysis was done by flow imaging cytometry.
110 Glycated HB (HbA1c): Model of assay: HA 8180. HbA1c was measured by HPLC with elution buffers A (Batch No. 3G1323) and B
111 (Batch No. 3E1331) and HB hemolytic agent for glycated HB (Batch No. 3J1563).

112 2.5.Study registration and Ethics review

113 Ethical Approval: The experimental protocol was designed in line with the ethical principles of the Declaration of Helsinki. The study
114 was approved by the Human Ethics Committee of the Clinical Trial Research Ethics Committee at the Yiyang Central
115 Hospital,Written informed consent was taken from each participant or their legal guardian. This RCT was registered at the Chinese
116 Clinical Trial Registry (ChiCTR2500098769) on 2025-03-13.

117 2.6.Blind method

118 In this study, the data recorder who obtained information on feeding windows via WeChat was aware of the group assignments and
119 corresponding outcomes, as this individual allocated participants into two groups.Nurses were unaware of the subjects' grouping when

collecting blood samples. laboratory testing and statistical analysis were conducted by different physicians, all of whom were blinded to the grouping conditions.

2.7.Statistical Analysis

Statistical analyses were done with the utilization of the statistical package of IBM-SPSS version 25.0. Normally distributed data are expressed as mean $\pm$ standard deviation ($X \pm S$). Between-group comparisons of normally distributed data were conducted using independent sample t-tests and paired t-tests were used for comparisons of paired normally distributed data. Moreover, non-normally distributed data are displayed as median (P25, P75) and analyzed by Wilcoxon signed-rank test for paired comparisons. Categorical data was compared using the Fisher's Freeman-Halton test. A 2-tailed P value < 0.05 was deemed statistically significant.

This randomized controlled trial was reported in accordance with the CONSORT 2025. A completed CONSORT checklist, with the manuscript section and page/paragraph number indicated for each item, is provided as an additional file. A CONSORT flow diagram illustrating participant recruitment, randomization, allocation, follow-up, and analysis is included as Figure 1.

3.Results

In this study, an RCT was conducted with 12 participants in each group, and within-group comparisons (pre- vs. post-intervention) were performed for both groups. In addition, a retrospective case-control analysis was done using baseline data from 41 participants who completed three weeks of dietary monitoring. In all analyses, the results suggest that TRF is effective in lowering total cholesterol (TC) levels in post-transplant patients.

3.1. Results of RCT

Of the 28 people who were initially assigned to the LTF group, four dropped out for various reasons. Of the 14 participants who were assigned to the 10-hour TRF regimen, 12 completed the 12-week intervention; one participant withdrew from the study because of a pulmonary infection, and one participant was unable to adhere to the 10-hour TRF schedule because of work constraints. Among the 14 subjects in the control group, one subject was excluded because of gastro-intestinal bleeding and one subject withdrew without giving a reason. Ultimately, 24 participants (13 male, 11 females; aged 25-66 years) were randomized to the LTF-to-TRF group (7 male, 5 female) and control group (6 male, 6 female). The average age of the LTF to TRF group was 50.00 ± 10.66 years and age of control group was 43.92 ± 12.42 years. Baseline characteristics were not substantially different between the 2 randomized groups (Table 1; Figure 2). Dyslipidemia was found in 83% (20/24) of participants, which is consistent with previous studies. Both groups were requested to adhere to a low-fat diet.

Following the 12-week intervention, there was no significant variance in TC levels between the two randomized groups. Nevertheless, the change in cholesterol (δ cholesterol) exhibited a substantial variance between the groups ($P = 0.001$; Supplementary Table 1), with the TRF group exhibiting a greater decrease in comparison to the non-time restricted group. No statistically substantial variances were found in other parameters, such as body weight, alteration in body weight (δ body weight), BMI, or change in BMI (δ BMI) between the two groups ($P > 0.05$) (Table 2; Figure 3).

3.2. Results of Self-Controlled Before-After Trial

Within-group comparisons (pre- vs. post-intervention) were done for each group. LTF-to-TRF group: Significant decreases were found in triglyceride (TG; $P=0.003$) and TC ($P=0.001$) levels after completion of the 12-week TRF intervention, suggesting that TRF may be an effective intervention to reduce these lipid parameters. There was also a substantial change in the amount of time the participants spent eating ($P < 0.001$) (Table 3; Figure 4). Control group: There were no statistically substantial variations in metabolic parameters after the non-time restricted feeding period ($P > 0.05$) (Table 4; Figure 5).

3.3. Results of Comparison of Baseline Values Between Two Groups

The baseline characteristics of 24 subjects were compared who finished the 12-week dietary intervention (LTF-to-TRF group, $n = 12$; control group, $n = 12$) with 17 kidney transplant recipients who habitually performed TRF. At baseline, the TRF group had a significantly shorter daily eating window (9.54 ± 0.68 hours) compared to LTF group (11.25 ± 0.80 hours, $P = 0.002$). No statistically substantial variances were revealed between the two groups in body weight, sex, age, fasting blood glucose, HbA1c, TG or low-density lipoprotein (LDL) cholesterol. However, TRF recipients had lower TC levels (5.04 ± 0.68 mmol/L) compared with the LTF group (5.79 ± 0.71 mmol/L), and this variance was statistically substantial ($P=0.002$) (Table 5; Figure 6).

Discussion

170 To our knowledge, this is the first RCT assessing the effects of TRF in kidney transplant recipients. The main objectives of this study
171 were: (1) to determine the feasibility of implementing a 10 h TRF intervention in kidney transplant recipients, and (2) to evaluate
172 changes in metabolic parameters following the intervention. Secondary outcomes were measurements of quality of life and other
173 cardiometabolic health measures.

174 Dietary management after kidney transplantation is imperative to ensure the health of the patient and optimal graft function. Different
175 dietary patterns may have different impacts in this population, and several postoperative dietary intervention models have attracted
176 attention in the past years: Plant-based diets: Plant-based dietary patterns have shown beneficial effects on renal function. Increased
177 consumption of fruits and vegetables is inversely linked with proteinuria and may delay progression of end-stage renal disease and
178 may potentially enhance survival rates [9-12]. Intermittent fasting: Intermittent fasting is not only great for obesity management, but it
179 can also treat metabolic disorders. Multiple studies have reported that this dietary approach decreases insulin resistance, body weight,
180 body fat, visceral and ectopic fat accumulation and adipocyte size, improves metabolic flexibility, with no significant evidence of
181 adverse effects [13]. Low-carbohydrate diets: Ketogenic diets (KD) have been linked to developments in cardiovascular risk factors,
182 such as type 2 diabetes, HDL cholesterol levels, and obesity. Some studies also suggest that KD may suppress the growth of renal
183 cysts and suppress inflammation and fibrosis [14]. Juicing diets: Juicing interventions can have a significant effect on the gut
184 microbiota. The relative abundance of the microbe group called the Firmicutes, which are linked with immune dysregulation and
185 obesity, decreases while Bacteroidetes, linked with better cardiovascular health, declined obesity and inflammatory pathways'
186 regulation, increases. These microbial changes could be a contributor to improved post-transplant outcome [15-17]. While these

187 dietary patterns have shown benefits in reducing cardiovascular risk, having anti-inflammatory effects and promoting weight loss, they
188 tend to have strict restrictions on what foods are allowed. In areas with multiple dietary cultures, such restrictions may be limiting to
189 long-term adherence. Therefore, encouraging a post-transplant dietary pattern that is both healthy and sustainable is necessary to
190 achieve long-term improvements in patient health and graft function.

191 TRF has become a very popular feeding pattern in recent years. It is an attempt to manage body weight by constraining food intake to
192 a particular time of day and only drinking water or tea during the off-hours. In our study, 14 people were assigned to a 10-hour TRF
193 regimen, of whom 12 completed the 12-week intervention. One participant withdrew because of pulmonary infection and another was
194 unable to adhere to the TRF schedule because of work constraints. In the control group, two participants withdrew, one because of
195 gastrointestinal bleeding and the other because of a reason not specified. Our findings have suggested that the adherence to TRF in
196 kidney transplant recipients may decrease tri-glyceride and TC levels, suggesting that TRF may be a non-pharmacological approach in
197 preventing obesity and associated metabolic disorders [18]. Importantly, TRF did not increase the risk of adverse events (AEs),
198 including infections related to immunosuppression, graft rejection, gastrointestinal bleeding or diarrhea and no serious AEs were
199 attributable to the intervention. Two AEs were reported as unlikely related to TRF (one case of acquired pneumonia in the TRF group
200 and one case of gastrointestinal bleeding in the control group). Overall, 85% of participants completed the full 3-month TRF regimen
201 without any TRF attributable adverse effects, supporting the feasibility of implementing a 10-hour TRF dietary intervention in kidney
202 transplant recipients.

In the general population, TRF has been shown to regulate metabolic cycles, control body weight and prevent type 2 diabetes, cardiovascular diseases, diet-induced obesity, and other metabolic conditions without the need for caloric restriction [19-22]. Furthermore, TRF does not seem to have a negative impact on the gut microbiota composition or cause gastrointestinal disorders [23].

For kidney transplant recipients, TRF may have a number of other benefits:

1. Improvement of metabolic function: TRF can improve glycemic control and insulin resistance. In the prediabetic state, early time-restricted feeding enhances blood pressure, insulin sensitivity, and oxidative stress, even in the absence of weight loss, promoting pancreatic β -cell function [24]. Consequently, TRF may prevent post-transplant diabetes mellitus.
2. Reduction of inflammation: Overconsumption of nutrients can cause inflammatory reactions, which can interfere with glucose and lipid metabolism [25]. TRF has been reported to reduce inflammatory markers, suppress inflammation and modulate immunity [26], which could help reduce the risk of rejection episodes and other complications associated with inflammation in kidney transplant recipients.
3. Body weight management: Kidney transplant recipients are at risk of weight gain because of immunosuppressive drugs, especially corticosteroids. TRF offers the benefit of a structured eating window that may help to mitigate the weight gain without the need for complete dietary restriction.

It is imperative to note that TRF does not involve complete dietary restriction. Kidney transplant recipients need to be sure that they are getting enough protein and essential vitamins during the eating window to avoid malnutrition and keep their immune systems functioning. Furthermore, many transplant patients need to be given immunosuppressive medications on time, and TRF could theoretically affect drug absorption and efficacy. Although our study did not show any significant effect of TRF on medication absorption or timing, consultation with a transplant physician is advised before a change in dietary patterns. Finally, dietary

modifications after transplantation must be considered in the context of renal function, immunosuppressive therapy, and possible complications, such as infection, rejection, gastrointestinal bleeding, and diarrhea. Regular monitoring of renal function is crucial to ensure the long-term health of the graft while implementing dietary interventions like TRF.

ASCVD, which includes coronary atherosclerotic heart disease, stroke and other peripheral vascular diseases, has become a major cause of graft failure and recipient mortality in kidney transplant recipients [1, 2, 27]. Dyslipidemia is a major pathogenic factor in ASCVD and solid organ transplant recipients are especially vulnerable because of the nature of their treatment. Post-transplant dyslipidemia is reported in up to 80% of patients [2], which is similar to our study in which 83% (20/24) of participants had dyslipidemia. For kidney transplant recipients, a low-fat diet is recommended, as long as nutritional adequacy is preserved. In our RCT, after 12 weeks of TRF, there was no substantial variance in lipid levels between the TRF and control group. However, the difference in TC (δ cholesterol) was significantly different between groups ($P = 0.001$). This may reflect the relatively short duration of the intervention and longer-term studies may show more pronounced improvements in lipid profiles and this warrants further study. Within-group analyses showed that the participants in the LTF-to-TRF group showed significant reductions in TG ($P = 0.003$) and TC ($P = 0.001$) after the TRF intervention, indicating that TRF may be effective in improving lipid metabolism. There was also a significant ($P < 0.001$) change in the daily eating window. In contrast, participants in the control group, who continued their LTF pattern, did not show significant changes in metabolic parameters over the study period ($P > 0.05$). These findings indicate that the implementation of TRF in kidney transplant recipients can beneficially influence lipid metabolism and possibly reduce cardiovascular risk. Furthermore, we compared baseline characteristics of the 24 participants who completed the 12-week intervention (LTF-to-TRF,

n = 12; control, n = 12) with 17 kidney transplant recipients who performed TRF habitually. TRF recipients had significantly lower TC (5.04 ± 0.68 mmol/L) than the LTF group (5.79 ± 0.71 mmol/L, $P = 0.002$) and had a shorter daily eating window (9.54 ± 0.68 hours vs. 11.25 ± 0.80 hours, $P = 0.002$). Collectively, these results suggest that a 10-hour TRF regimen may assist in decreasing blood lipid levels, preventing the development of obesity and dyslipidemia-related ASCVD, and may even improve long-term survival in kidney transplant recipients.

The high incidence of dyslipidemia after kidney transplantation is closely related to the use of immunosuppressive agents after transplantation. These medications can cause changes in the way lipids are metabolized, resulting in varying levels of increased cholesterol and TG, often in a dose-dependent fashion. Commonly used immunosuppressants are glucocorticosteroids, CNIs (e.g., tacrolimus and cyclosporine) and mammalian target of rapamycin inhibitors (mTORi; e.g., everolimus and sirolimus). Glucocorticoids raise very LDL (VLDL), TC and TG, and lower HDL. Mechanistically, glucocorticoids promote lipolysis, suppress lipogenesis, raise blood glucose, promote lipid metabolism at the expense of glucose metabolism, promote insulin resistance and contribute to metabolic syndrome. Long-term use has a cumulative effect. CNIs, both cyclosporine and tacrolimus, cause an increase in LDL and TC by decreasing bile acid synthesis, downregulating LDL receptor function, constraining cholesterol clearance, enhancing the conversion of VLDL to LDL, and stimulating cholesterol synthesis. When combined with glucocorticoids, their lipid-elevating effects are enhanced, although tacrolimus usually has less effect on lipid levels than cyclosporine. mTOR inhibitors, such as sirolimus and everolimus, elevate TC and TG by stimulating hepatic lipid synthesis, decreasing lipid clearance, and inhibiting insulin-like growth factor and insulin signaling pathways [28-31].

Of the 14 participants who were assigned to the 10-hour TRF regimen, 1 participant withdrew because of pulmonary infection. This patient had been on long-term quadruple immunosuppressive therapy that included tacrolimus, sirolimus, mycophenolate mofetil, and low-dose corticosteroids. At baseline, the patient had dyslipidemia, manifested by hypercholesterolemia and hypertriglyceridemia, consistent with the known lipid-elevating effects of sirolimus. Previous studies have revealed that sirolimus leads to a rise in TC and TG by raising hepatic lipid synthesis, decreasing lipid clearance, and inhibiting insulin-like growth factor and insulin signaling pathways [28-31]. Upon follow-up about 50 days into the intervention, the patient's lipid levels were back in the normal range. The patient later withdrew from the study in the middle of the intervention more than two months later due to community-acquired pneumonia. Another participant who was also taking sirolimus had been habitually maintaining a 10-hour TRF pattern and their baseline lipid profile was within the normal range. Based on these observations, we hypothesize that TRF may modulate lipid levels via pathways that involve insulin and insulin-like growth factor signaling. This hypothesis warrants further experimental investigation to elucidate the underlying mechanism.

This study has a number of limitations. First, although it was a randomized trial, participants were not blinded to the intervention, which may introduce performance bias. Second, our inclusion criteria were that participants had a serum creatine fluctuation of less than 20% over three consecutive follow-up tests and an eGFR >30 mL/min/1.73 m². These criteria may reduce the generalizability of our findings and create selection bias. Third, the sample size was relatively small and participants may not represent the general population, multicenter studies with bigger sample sizes been desirable to confirm our results. Fourth, potential barriers to adherence

to TRF were not systematically analyzed. Fifth, although participants in the TRF group were educated to consume all food within a 10-hour window, the timing and duration of the eating window differed among individuals, which may have influenced outcomes. In summary, TRF following kidney transplantation may have positive metabolic benefits. TRF has the potential to improve metabolic function, help with weight management and decrease the risk of obesity and dyslipidemia-related ASCVD, potentially improving long-term survival in kidney transplant recipients. However, given the individual variability and specific needs of renal transplant patients, close collaboration with healthcare providers is necessary to ensure that TRF is safe and effective. Dietary changes should take into account the patient's overall health, drug regimen, and nutritional needs. Currently, there is limited evidence on the implementation of TRF in kidney transplant recipients, and more clinical studies are required to determine its safety and efficacy.

Conclusion(s)

Time-restricted feeding is a feasible dietary intervention that may be helpful in reducing dyslipidemia in kidney transplant recipients.

Abbreviations:

ASCVD: atherosclerotic cardiovascular disease

TC: total cholesterol

TG: triglyceride

TRF: time-restricted feeding

LTF: long-time feeding

VLDL: very low density lipoprotein

LDL: low density lipoprotein

HDL: high-density lipoprotein

HbA1c: glycated hemoglobin A1c

BMI: Body mass index

CNI: calcineurin inhibitor

LTF to TRF: long-time feeding in baseline, and underwent time-restricted feeding during the intervention period

LTF to LTF: long-time feeding in baseline, and continued to maintain this dietary pattern

Declaration

Ethics approval and consent to participate

The experimental protocol was designed in line with the ethical principles of the Declaration of Helsinki. The study was approved by the Human Ethics Committee of the Clinical Trial Research Ethics Committee at the Yiyang Central Hospital, Written informed consent was taken from each participant or their legal guardian.

Consent for publication

All subjects participating in the experiment were required to sign an informed consent form, acknowledging and agreeing that their personal data from this study would be used for writing the research article.

Data availability statement:

The statement clarifies that the de-identified individual participant data underlying this study will be made available upon reasonable request to the corresponding author, pending approval by the Institutional Review Board and execution of a data access agreement, to ensure compliance with participant privacy protection regulations.

Declaration of competing interests:

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this manuscript.

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Author Contributions

Liu Dikuan designed research; Yang Tie, Zhuang Quanhui, and Zhan Yuqi acquired and analyzed data; Xiong Lie had primary responsibility for final content. All authors have read and approved the final manuscript.

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Declaration of AI and AI-assisted Technologies:

We promise that no AI or AI-assisted technologies have been used in this paper.

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Tables

Table 1. Randomized controlled trial of LTF to TRF and LTF to LTF pre-intervention.

		LTF to LTF (n=12)	LTF to TRF (n=12)	Difference between Groups (95% CI)	P value
Gender	Male	6 (50%)	7 (58.3%)		0.50
	Female	6 (50%)	5 (41.7%)		
Age (years)		43.92±12.42	50±10.66	-6.08 (-15.88to3.72)	0.21
Height (cm)		160.38±8.07	163±8.21	-2.63 (-9.52 to 4.27)	0.73
Weight (kg)		58.38±10.99	60±11.62	-1.63 (-11.20 to 7.95)	0.73
BMI(kg/m2)		22.68±4.04	22.58±3.09	0.098 (-2.95 to 3.14)	0.95
Waist circumference (cm)		83.20±10.81	84.88±8.02	-1.67 (-9.76 to 6.43)	0.67
Hip Circumference (cm)		93.83±6.90	94.29±5.08	-0.46 (-5.59 to 4.67)	0.86
Feeding window (h)		11.44±0.88	11.07±0.71	0.37(-0.30 to 1.05)	0.27
Blood sugar (mmol/L)		5.515 (5.3125,6.03)	5.075 (4.575,5.505)		0.09
Albumin (g/L)		45.37±2.32	45.63±1.97	-0.26 (-2.08 to 1.57)	0.77
Median (IQR) HbA1c (mmol/L)		5.45 (5.2,5.6)	5.35 (5.15,5.525)		0.54
Median (IQR)TG (mmol/L)		1.66 (1.3225, 2.0325)	1.665 (1.205, 2.1725)		0.91
TC (mmol/L)		5.58±0.81	5.99±0.55	-0.41 (-1.00 to 0.18)	0.16

HDL (mmol/L)		1.62±0.48	1.84±0.43	-0.22 (-0.60 to 0.17)	0.26
LDL (mmol/L)		3.13±0.94	3.26±0.89	-0.14 (-0.70 to 0.14)	0.71
Hb (g/L)		135±26.06	134.25±26.24	0.75 (-21.39 to 22.89)	0.77
Cr (μmol/L)		106.67±27.89	128.58±29.18	-21.92 (-46.08 to 2.25)	0.073
BUN (μmol/L)		9.27±3.43	9.35±3.53	-0.08 (-3.03 to 2.86)	0.95
SBP (mmHg)		130.67±11.396	133.67±15.79	-3 (-14.66 to 8.66)	0.35
DBP (mmHg)		84.67±7.83	87.83±8.44	-3.16 (-10.6 to 3.72)	0.35
HR (beats/min)		77.33±9.54	79.92±7.19	-2.58 (-9.74 to 4.57)	0.46
Median (IQR)time since transplant (months)		17.5 (11.5,45)	51.42±68.95		0.47
Lipid-lowering drugs	use	2 (16.7%)	4 (33.3%)		0.32
	non-use	10 (83.3%)	8 (66.7%)		
Antihypertensive drugs	ues	10 (83.3%)	9 (75%)		0.50
	non-use	2 (16.7%)	3 (25%)		

Abbreviations: ▲Plus–minus values are means ±SD. Patients were assigned to LTF to TRF(10-HTRF, eating within any 10 hours per day, without interference with energy intake) or LTF to LTF(continue to maintain the current diet). IQR denotes interquartile range. BMI: body mass index, HbA1c: glycated hemoglobin A1c, Hb: hemoglobin, TG: triglyceride, TC: total cholesterol, HDL: high-density lipoprotein, LDL: low density lipoprotein, Cr: creatinine, BUN: blood urea nitrogen, SBP: systolic blood pressure, DBP: diastolic blood pressure, HR: heart rate.*P<0.05, **P<0.01, ***P<0.001.

Table 2. Randomized controlled trial of LTF to TRF and LTF to LTF post-intervention.

	LTF to TRF (n=12)	LTF to LTF (n=12)	Difference between Groups (95% CI)	P value
Feeding window (h)	9.71 (9.60, 9.8)	10.79 (10.64,11.28)		0.001**
Weight (kg)	60.58±11.94	58.75±11.83	1.83 (-8.23 to 11.90)	0.71
Δ Weight (kg)	0.58±1.44	0.38±1.25	0.21 (-0.93 to 1.35)	0.71
BMI(kg/m2)	22.79±3.17	22.91±4.33	-0.12 (-3.33 to 3.10)	0.94
Median (IQR) Δ BMI(kg/m2)	0 (-0.09,0.4625)	0 (-0.23,0.785)		0.87
Waist circumference (cm)	85.13±8.12	83.29±10.80	1.83 (-6.3 to 10.01)	0.65
Δ Waist circumference (cm)	0.25±0.58	0.08±0.63	0.17 (-0.35 to 0.68)	0.51
Hip Circumference (cm)	94.17±4.73	94.25±7.24	-0.083 (-5.26 to 5.09)	0.97
Δ Hip Circumference (cm)	-0.13±1.19	0.42±0.97	-0.54 (-1.46 to 0.38)	0.24
Median (IQR)blood sugar (mmol/L)	5.285 (4.93, 5.5475)	4.915 (4.685, 5.075)		0.11
Median (IQR) Δ blood sugar (mmol/L)	-0.38 (-0.835,0.08)	-0.02 (-0.2625,0.2475)		0.25
Albumin (g/L)	45.42±2.31	45.51±2.74	-0.92 (-2.24 to 2.05)	0.93
Δ Albumin (g/L)	-0.21±2.17	0.14±2.55	-0.35 (-2.36 to 1.66)	0.72
Median (IQR)HbA1c (mmol/L)	5.5 (5.25,5.65)	5.65 (5.575,5.8)		0.29
Median (IQR)ΔHbA1c (mmol/L)	0.05 (-0.025,0.2)	0.3 (0.05,0.625)		0.13
Median (IQR)TG (mmol/L)	1.31 (0.77, 1.44)	1.42 (1.07, 1.925)		0.21
Δ TG (mmol/L)	-0.38±0.35	-0.07±0.77	-0.32 (-0.82 to 0.19)	0.21
TC (mmol/L)	5.44±0.65	5.78±0.72	-0.33 (-0.24 to 0.91)	0.24
Δ TC (mmol/L)	-0.55±0.45	0.19±0.49	-0.78 (-1.21 to -0.34)	0.001**

HDL (mmol/L)	1.86±0.38	1.83±0.42	0.025 (-0.31 to 0.36)	0.88
δ HDL (mmol/L)	0.018±0.18	0.21±0.34	-0.19 (-0.42 to 0.04)	0.098
LDL (mmol/L)	2.79±0.42	3.16±0.73	-0.37 (-0.87 to 0.13)	0.14
δ LDL (mmol/L)	-0.48±0.84	0.027±0.58	-0.51 (-1.12 to 0.10)	0.1
Hb (g/L)	132±24.48	136.42±29.01	-4.42 (-27.14 to 18.31)	0.69
Median (IQR)δ Hb (g/L)	-3 (-11.25, 6)	2 (-1, 6.75)		0.34
Cr (μmol/L)	134.5±29.52	106.23±40.05	28.27 (-1.52 to 58.05)	0.63
Median (IQR)δ Cr (μmol/L)	5.5 (-1.75, 12)	5.5 (0,6)		0.63
BUN (μmol/L)	9.38±4.34	7.89±2.53	1.49 (-1.56 to 4.54)	0.32
δ BUN (μmol/L)	0.028±3.15	-1.38±2.24	1.41 (-0.90 to 3.72)	0.22
SBP (mmHg)	135.58±15.70	131.33±11.02	4.25 (-7.24 to 15.74)	0.45
δ SBP (mmHg)	1.92±4.72	0.67±4.21	1.25 (-2.54 to 5.04)	0.5
DBP (mmHg)	86±10.05	87.33±8.87	-1.83 (-5.64 to 1.97)	0.33
Median (IQR)δ DBP (mmHg)	-2.5 (-4,2.25)	3 (-4,4.5)		0.45
HR (beats/min)	81.33±6.68	79.08±10.18	2.25 (-5.04 to 9.54)	0.53
δ HR (beats/min)	1.42±2.79	1.75±2.38	-0.33 (-2.52 to 1.86)	0.76

Abbreviations: ▲ Plus–minus values are means ±SD. Patients were assigned to LTF to TRF(10-HTRF, eating within any 10 hours per day, without interference with energy intake) or LTF to LTF(continue to maintain the current diet). IQR denotes interquartile range. BMI: body mass index, HbA1c: glycated hemoglobin A1c, Hb: hemoglobin, TG: triglyceride, TC: total cholesterol, HDL: high-density lipoprotein, LDL: low density lipoprotein, Cr: creatinine, BUN: blood urea nitrogen, SBP: systolic blood pressure, DBP: diastolic blood pressure, HR: heart rate. *P<0.05, **P<0.01, ***P<0.001.

Table 3. LTF to TRF group's before-after trial.

	Pre-intervention	Post-intervention	Change from Groups (95% CI)	P value
Weight (kg)	60.00±11.62	60.58±11.94	0.58 (-0.33 to 1.50)	0.19
BMI(kg/m ²)	22.58±3.09	22.79±3.17	0.21 (-1.33 to 0.55)	0.21
Median (IQR) waist circumference (cm)	85 (79.5, 90.625)	85.75 (79.375, 90.625)		0.14
Hip Circumference (cm)	94.29±5.08	94.17±4.73	-0.30 (-0.74 to 0.13)	0.72
blood sugar (mmol/L)	5.73±1.12	5.43±0.88	-0.30 (-0.74 to 0.13)	0.15
Albumin (g/L)	45.63±1.97	45.42±2.31	-0.21 (-1.59 to 1.17)	0.75
HbA1c (mmol/L)	45.63±1.97	5.71±0.84	0.075 (-0.066 to 0.22)	0.27
TG (mmol/L)	1.68±0.68	1.30±0.64	-0.39 (-0.61 to -0.16)	0.003**
TC (mmol/L)	5.99±0.55	5.44±0.65	-0.55 (-0.84 to -0.26)	0.001**
HDL (mmol/L)	1.84±0.43	1.86±0.38	0.018 (-0.095 to 0.36)	0.73
LDL (mmol/L)	3.27±0.89	2.79±0.43	-0.48 (-1.01 to 0.051)	0.072
Hb (g/L)	134.25±26.24	132.00±24.48	-2.25 (-8.88 to 4.38)	0.47
Cr (μmol/L)	128.58±29.18	134.5±29.52	5.92 (-0.60 to 12.43)	0.071
BUN (μmol/L)	9.35±3.53	9.38±4.34	0.028 (-1.97 to 2.03)	0.98
SBP (mmHg)	133.67±15.79	135.58±15.70	1.92 (-1.08 to	0.19

			4.92)	
Median (IQR)DBP (mmHg)	85 (83.75, 91.25)	90.5 (81, 92)		0.72
HR (beats/min)	79.92±7.19	81.33±6.68	1.42 (-0.35 to 3.18)	0.105
Eating time (h)	11.44±0.88	9.82±0.54	-1.62 (-2.24 to - 1.004)	<0.001***

Abbreviations:▲Plus–minus values are means ±SD. IQR denotes interquartile range. BMI: body mass index, HbA1c: glycated hemoglobin A1c, Hb: hemoglobin, TG: triglyceride, TC: total cholesterol, HDL: high-density lipoprotein, LDL: low density lipoprotein, Cr: creatinine, BUN: blood urea nitrogen, SBP: systolic blood pressure, DBP: diastolic blood pressure, HR: heart rate. *P<0.05, **P<0.01, ***P<0.001.

Table 4. LTF to LTF group's before-after trial.

	Pre-intervention	Post-intervention	Change from Groups (95% CI)	P value
Weight (kg)	58.38±10.99	58.75±11.83	0.38 (-0.42 to 1.17)	0.32
BMI (kg/m ²)	22.68±4.04	22.91±4.33	0.23 (-0.12 to 0.58)	0.18
Median (IQR) waist circumference (cm)	85.25 (72.75, 91.375)	86 (72.75, 91.875)		0.58
Hip Circumference (cm)	93.83±6.90	94.25±7.24	0.42 (-0.20 to 1.04)	0.17
blood sugar (mmol/L)	5.09±0.65	4.96±0.68	-0.13 (-0.49 to 0.23)	0.45
Albumin (g/L)	45.37±2.32	45.51±2.74	0.14 (-1.48 to 1.76)	0.85
HbA1c (mmol/L)	5.34±0.37	5.64±0.50	0.3 (0.08 to 0.23)	0.011
TG (mmol/L)	1.95±1.20	1.88±1.36	-0.068 (-0.56 to 0.42)	0.76
TC (mmol/L)	5.58±0.81	5.78±0.72	0.19 (-0.12 to 0.50)	0.2
HDL (mmol/L)	1.62±0.48	1.83±0.42	0.21 (-0.002 to 0.42)	0.052
LDL (mmol/L)	3.13±0.94	3.16±0.73	0.027 (-0.34 to 0.40)	0.88
Median (IQR)Hb (g/L)	131.5 (121.75, 146.5)	132.5 (119.75, 155.75)		0.23
Cr (μmol/L)	106.23±27.89	106.23±40.05	-0.43 (-13.26 to 12.39)	0.94

BUN (μmol/L)	8.77±2.71	8.23±2.17	-0.55 (-1.72 to 0.63)	0.33
SBP (mmHg)	130.67±11.40	131.33±11.02	0.67 (-2.01 to 3.34)	0.59
DBP (mmHg)	84.67±7.83	86.00±10.05	1.33 (-1.56 to 4.23)	0.33
HR (beats/min)	77.33±9.54	79.08±10.18	1.75 (0.24 to 3.26)	0.027*
Eating time (h)	11.07±0.71	10.89±0.72	0.59 (-0.56 to 0.20)	0.32

Abbreviations: ▲Plus-minus values are means ±SD. IQR denotes interquartile range. BMI: body mass index, HbA1c: glycated hemoglobin A1c, Hb: hemoglobin, TG: triglyceride, TC: total cholesterol, HDL: high-density lipoprotein, LDL: low density lipoprotein, Cr: creatinine, BUN: blood urea nitrogen, SBP: systolic blood pressure, DBP: diastolic blood pressure, HR: heart rate. *P<0.05, **P<0.01, ***P<0.001.

Table 5. Pre-intervention: TRF vs. LTF.

		TRF (n=17)	LTF (n=24)	Difference between Groups (95% CI)	P value
Gender	Male	8 (47.1%)	13 (54.2%)		0.65
	Female	9 (52.9%)	11 (45.8%)		
Age (years)		41.94±8.76	46.96±11.74	-5.02 (-11.83 to 1.79)	0.14
Height (cm)		162.06±8.54	161.69±8.07	0.37 (-5.01 to 5.75)	0.89
Weight (kg)		56.15±9.62	59.19±11.09	-3.04 (-9.78 to 3.70)	0.37
BMI(kg/m ²)		21.46±3.12	22.63±3.52	-1.17 (-3.32 to 0.99)	0.28
Waist circumference (cm)		81.59±8.40	84.04±9.35	-2.45 (-8.20 to 3.30)	0.39
Hip Circumference (cm)		92.32±5.48	94.06±5.93	-1.74 (-6.43-1.95)	0.35
Feeding window (h)		9.54±0.68	11.25±0.80	-1.71(-2.20 to -1.23)	<0.001** *
Median (IQR)blood sugar (mmol/L)		5.27 (5.01, 5.45)	5.42 (4.7625, 5.725)		0.64
Albumin (g/L)		46.11±2.87	45.50±2.11	0.62 (-0.95 to 2.19)	0.43
Median (IQR)HbA1c (mmol/L)		5.3 (5.1, 5.4)	5.4 (5.15, 5.6)		0.72
Median (IQR)TG		1.42 (1.09, 1.7)	1.665 (1.205, 2.1075)		0.29

(mmol/L)					
TC (mmol/L)		5.04±0.68	5.79±0.71	-0.75 (-1.20 to -0.30)	0.002**
HDL (mmol/L)		1.71±0.37	1.72±0.46	-0.025 (-0.30 to 0.25)	0.86
LDL (mmol/L)		2.94±0.69	2.97±0.61	-0.38 (-0.90 to 0.15)	0.153
Hb (g/L)		131.24±15.94	134.24±25.58	-3.39 (-17.58 to 10.81)	0.63
Cr (μmol/L)		120.94±30.83	116.13±31.75	4.82 (-15.30-24.93)	0.63
BUN (μmol/L)		9.12±3.1	9.31±3.4	-0.19 (-2.30 to 1.91)	0.85
SBP (mmHg)		126.06±14.3	132.17±13.55	-6.11 (-15.00 to 2.78)	0.17
DBP (mmHg)		88.41±10.11	86.25±8.13	2.85 (-3.61 to 7.93)	0.45
HR (beats/min)		79.4±7.37	78.63±8.37	0.79 (-4.32 to 5.90)	0.76
Time since transplant (months)		25 (15, 35)	27 (14.25, 72)	23.287 (-53.58 to 7.00)	0.58
Lipid-lowering drugs	use	3 (17.6%)	6 (25%)		0.86
	non-use	14 (82.4%)	18 (75%)		
Antihypertensive drugs	uses	15 (88.2%)	19 (79.2%)		0.74
	non-use	2 (11.8%)	5 (20.8%)		

Abbreviations: ▲Plus-minus values are means ±SD. IQR denotes interquartile range. BMI: body mass index, HbA1c: glycated hemoglobin A1c, Hb: hemoglobin, TG: triglyceride, TC: total cholesterol, HDL: high-density lipoprotein, LDL: low density lipoprotein, Cr: creatinine, BUN: blood urea nitrogen, SBP: systolic blood pressure, DBP: diastolic blood pressure, HR: heart rate. *P<0.05, **P<0.01, ***P<0.001.

Figure 1:A flowchart of this study

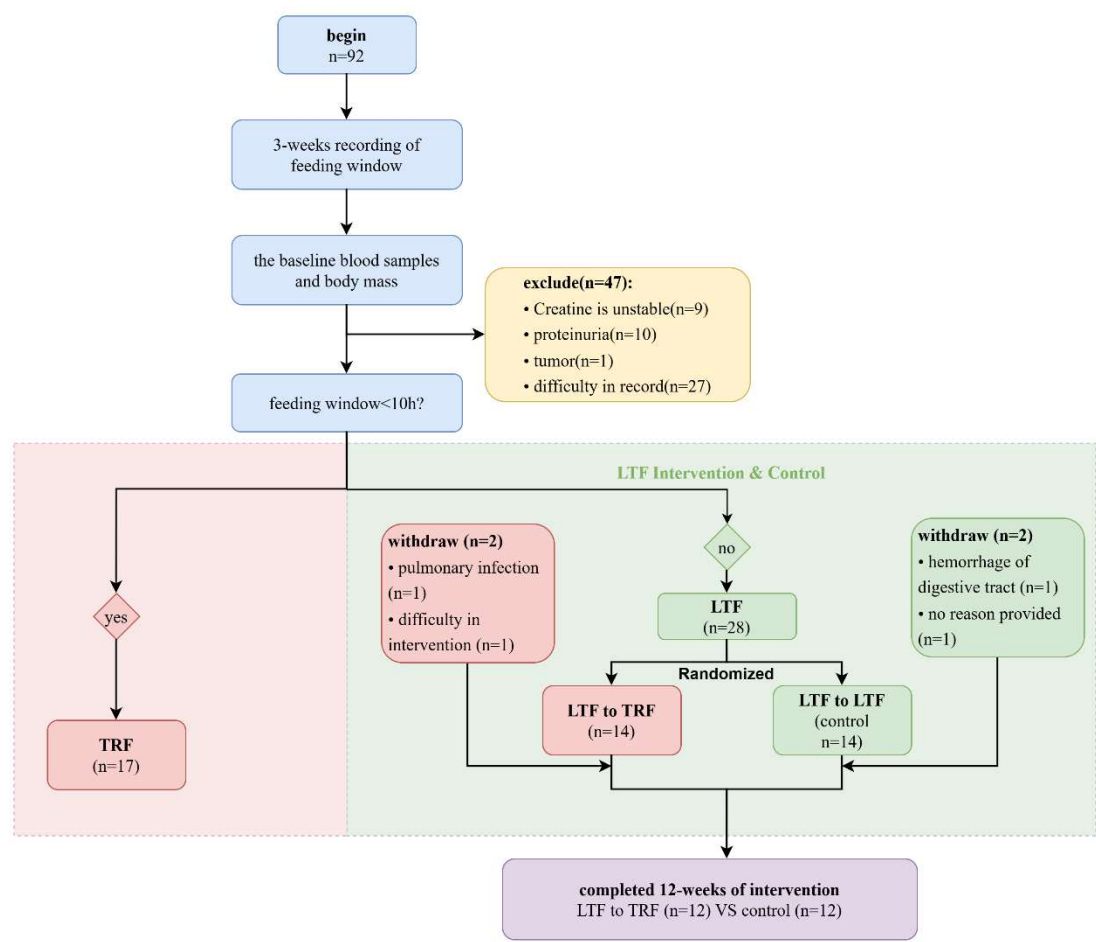


Figure 2: Baseline randomized controlled trials in the pre-intervention LTF to TRF and LTF to LTF groups. n = 12 participants in LTF to TRF group, n = 12 participants in LTF to LTF group. Metabolic risk factors (A triglyceride; B total cholesterol; C high-density lipoprotein; D low density lipoprotein; E# blood sugar; F#HbA1c) were not statistically different between LTF to TRF group and LTF to LTF group. #Wilcoxon rank-sum test.

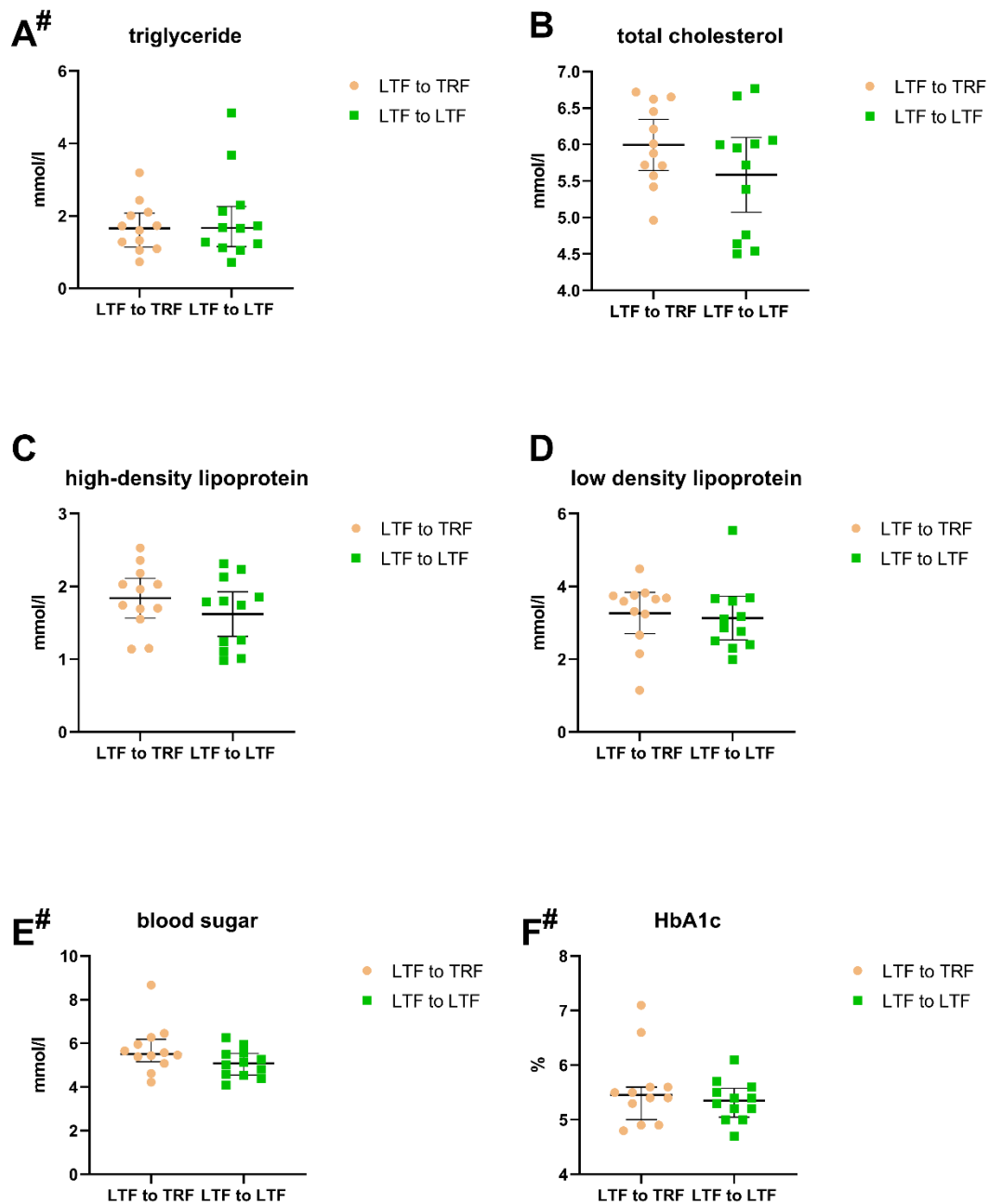


Figure 3: Randomized controlled trial of LTF to TRF and LTF to LTF after intervention. $n = 12$ participants in LTF to TRF group, $n = 12$ participants in LTF to LTF group. D δ total cholesterol was statistically different between LTF to TRF group and LTF to LTF group after intervention, $**P = 0.001$. A# triglyceride; B δ triglyceride; C total cholesterol; E high-density lipoprotein; F δ high-density lipoprotein; G low density lipoprotein; H δ low density lipoprotein; I# blood sugar; J# δ blood sugar; K# HbA1c; L# δ HbA1c were not statistically different between LTF to TRF group and LTF to LTF group after intervention.# Wilcoxon rank-sum test. $*P < 0.05$, $**P < 0.01$, $***P < 0.001$.

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Figure 4: LTF to TRF group's before-after trial. n = 12 participants in LTF to TRF group. A Triglyceride was statistically different between outcome and baseline, $**P=0.003$. B Total cholesterol was statistically different between outcome and baseline, $*P=0.001$. C high-density lipoprotein; D low density lipoprotein; E blood sugar; F HbA1c were not statistically different between outcome and baseline. $*P<0.05$, $**P<0.01$, $***P<0.001$.

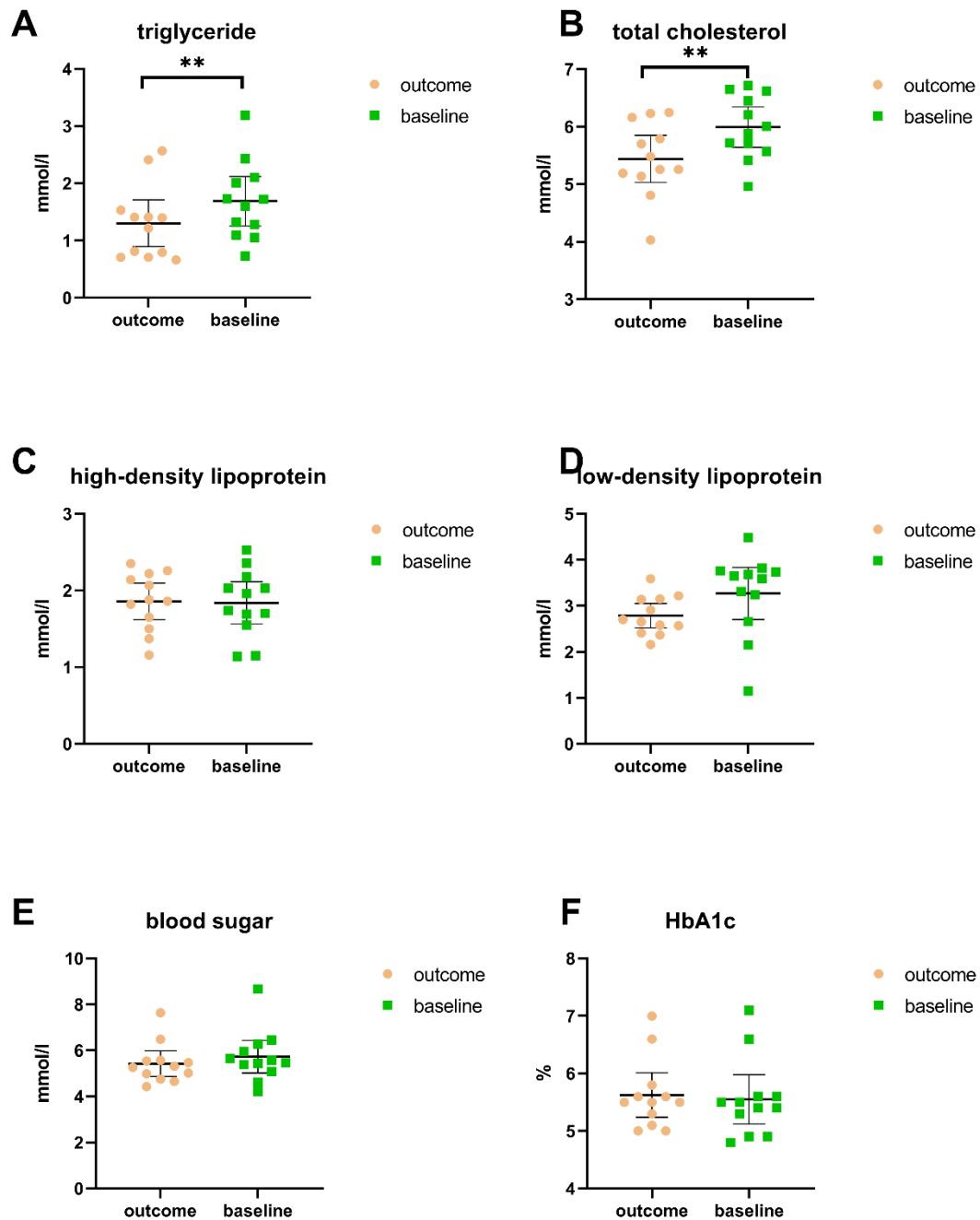


Figure 5: LTF to LTF group's before-after trial. n = 12 participants in LTF to LTF group. A triglyceride; B total cholesterol; C high-density lipoprotein; D low density lipoprotein; E blood sugar; F HbA1c were not statistically different between outcome and baseline.

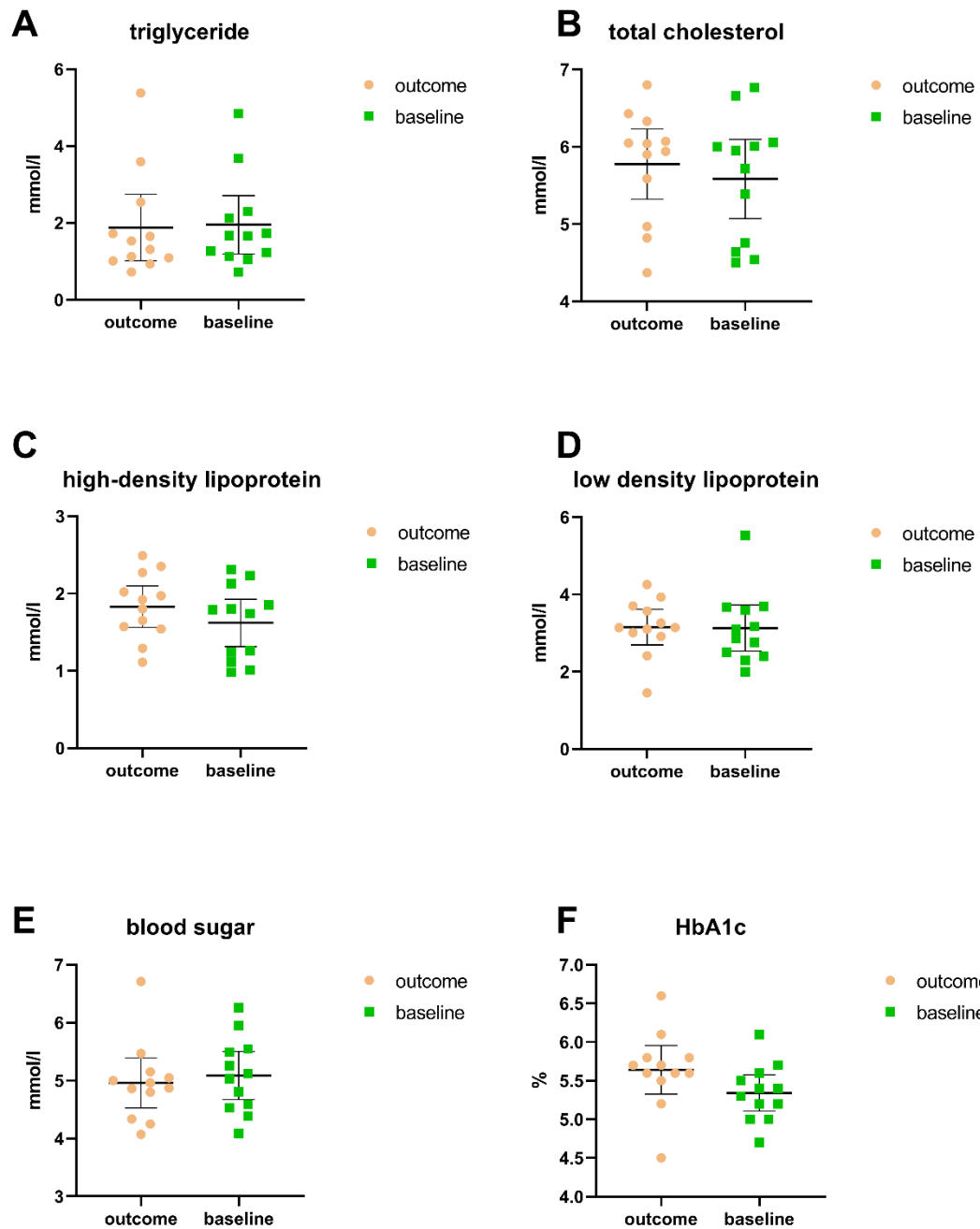
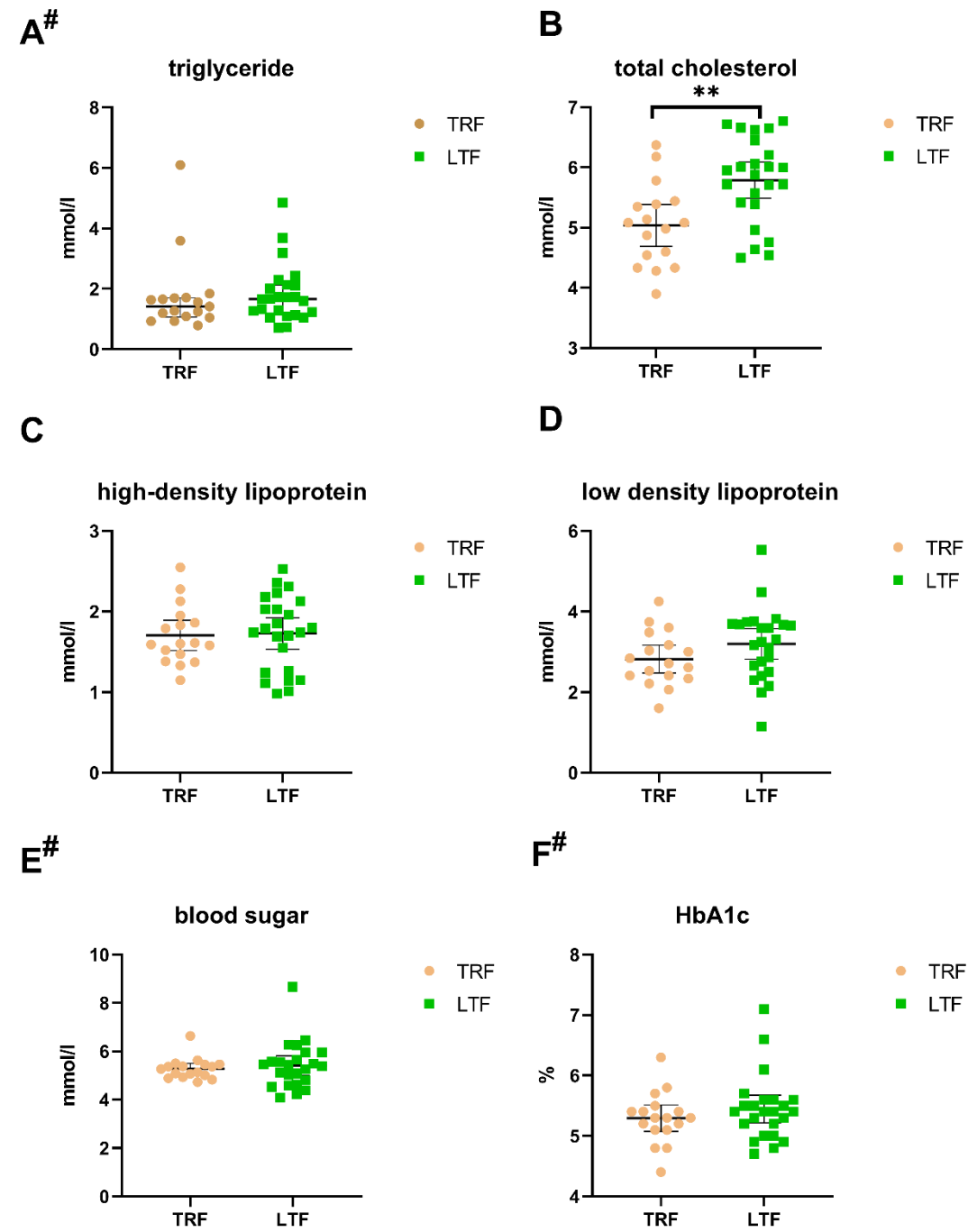


Figure 6: Baseline measures of 24 LTF renal recipients compared with 17 TRF renal recipients. B total cholesterol was statistically different between TRF and LTF, $**P=0.002$. A[#] triglyceride; C high-density lipoprotein; D low density lipoprotein; E[#] blood sugar; F[#] HbA1c were not statistically different between TRF and LTF. [#]Wilcoxon rank-sum test. $*P<0.05$, $**P<0.01$, $***P<0.001$.



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