ORIGINAL RESEARCH

A Randomized Controlled Trial of an Intensive Nutrition Intervention Versus Standard Nutrition Care to Avoid Excess Weight Gain After Kidney Transplantation: The INTENT Trial

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Objective: Excessive weight gain is common after kidney transplantation and increases cardiovascular risk. The aim of this randomized controlled trial was to determine whether an intensive nutrition and exercise intervention delivered alongside routine post-transplant care would reduce post-transplant weight gain.

Design: Single-blind, randomized controlled trial.

Subjects and Setting: Adult kidney transplant recipients at a regional transplant center were recruited during routine outpatient clinic visits in the first month after transplant. Patients with a body mass index >40 kg/m^2 or <18.5 kg/m^2, severe malnutrition, or ongoing medical complications were excluded.

Intervention: Participants were randomized to intensive nutrition intervention (individualized nutrition and exercise counselling; 12 dietitian visits; 3 exercise physiologist visits over 12 months) or to standard nutrition care (guideline based; 4 dietitian visits).

Main outcome measures: The primary outcome was weight at 6 months after transplant adjusted for baseline weight, obesity, and gender, analyzed using analysis of covariance. The secondary outcomes included body composition, biochemistry, quality of life, and physical function.

Results: Thirty-seven participants were randomized to the intensive intervention (n = 19) or to standard care (n = 18); one intensive group participant withdrew before baseline. Weight increased between baseline, 6 and 12 months (78.0 ± 13.7 [standard deviation], 79.6 ± 13.0 kg, 81.6 ± 12.9 kg; mean change 4.6% $P < .001$) but at 6 months did not differ significantly between the groups: 77.0 ± 12.4 kg (intensive); 82.2 ± 13.4 kg (standard); difference in adjusted means 0.4 kg (95% confidence interval: −2.2 to 3.0 kg); analysis of covariance $P = .7$. No between-group differences in secondary outcomes were observed. Across the whole cohort, total body protein and physical function (gait speed, sit to stand, grip strength, physical activity, and quality of life [all but 2 domains]) improved. However, adverse changes were seen for total body fat, HbA1c, and fasting glucose across the cohort.

Conclusions: Kidney transplant recipients in the first year after transplant did not benefit from an intensive nutrition intervention compared with standard nutrition care, although weight gain was relatively modest in both groups.

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Introduction

DESPITE SUBSTANTIALLY IMPROVED outcomes compared with patients on dialysis, kidney transplant recipients have significantly reduced survival compared with the age-matched general population.[1] This is predominantly due to an increased risk of cardiovascular disease (CVD).[2,3] Excessive weight gain, obesity, and diabetes are important risk factors for CVD, and obesity is associated with increased risks of graft loss and death.[4]

Significant weight gain is common in kidney transplant recipients, particularly in the first year after transplant.[5–7] The extent of weight gain varies, but increases of >10% of baseline weight are not unusual.[6,8] Studies on body composition after transplant implicate increased total body fat, rather than lean muscle mass, as the major contributor to weight gain.[6,9–11] Multiple factors have been associated with post-transplant weight gain, including relaxation of dietary restrictions,[6,9–13] increased appetite and well-being,[6] immunosuppressive medications (steroids),[14] female gender,[7] and inadequate physical activity.[8,15] Importantly, excessive weight gain after transplant is associated with adverse long-term health outcomes, including new-onset diabetes after transplant, graft failure, and cardiovascular and all-cause mortality.[13,16,17]

Weight gain after transplant is a potentially modifiable risk factor for poor outcomes and thus an appropriate target for therapeutic interventions. Studies in the general population have shown that interventions addressing nutrition, behavior, and physical activity promote weight loss in obese patients[18–20] and that those that involve frequent reviews (eg, fortnightly for 3 months and monitoring for at least 12 months) have shown the greatest benefits.[21,22] In kidney transplant recipients, there is currently a lack of evidence from randomized controlled trials (RCTs) to inform clinical practice.[12,23,24] Studies on nutrition interventions after transplant are inconclusive and limited by inadequate study designs.[25,26]

The effect of Intensive Nutrition Interventions on Weight Gain After Kidney Transplantation (INTENT) trial was an RCT which aimed to determine whether an early intensive nutrition intervention, including physical activity advice, could reduce weight gain and improve body composition, physical activity, and other important measures, compared with standard care in the first year after kidney transplant.

Materials and Methods

Study Overview

The design and methodology of the INTENT trial have been described previously.[27] INTENT was a single-blind RCT, conducted at a regional transplant center that provides transplantation for a population of approximately 2.6 million. The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12614000155695). Figure 1 shows the trial outline. The study was reviewed and received ethical approval from the Northern B Health and Disability Ethics Committee (14/NTB/8). All participants provided written informed consent.

Participants

Adult kidney transplant recipients residing in the Auckland region were recruited during the first month following

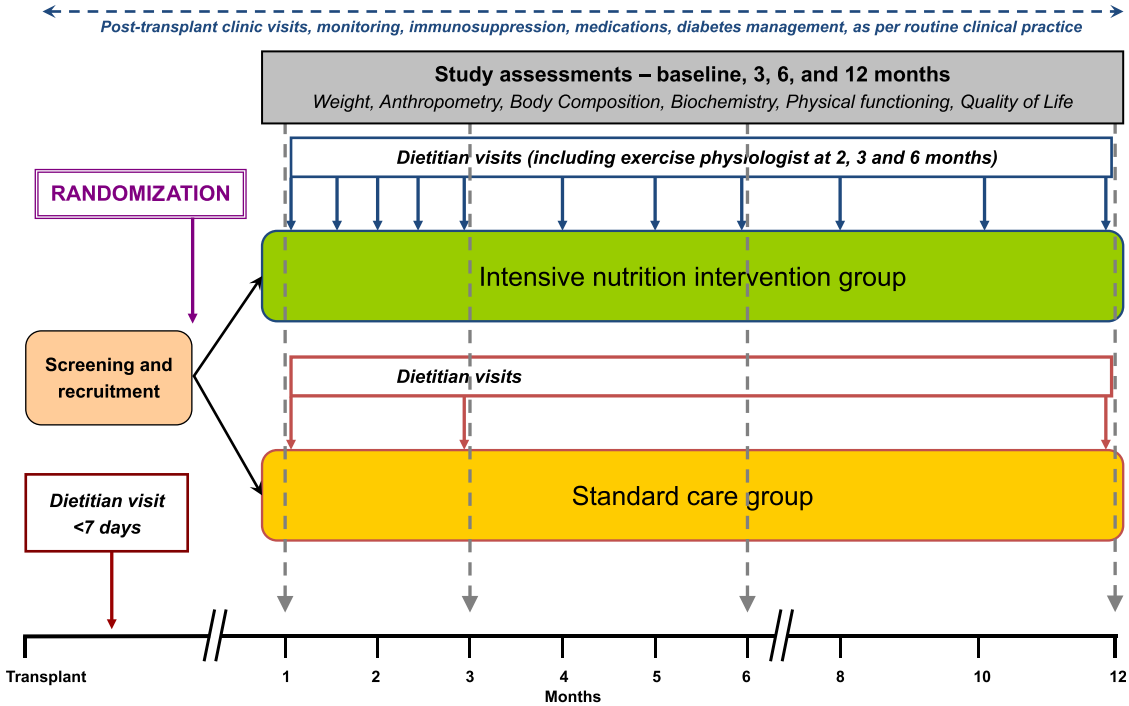

Figure 1. Study design and flowchart. Ryan et al. (2014)[27]

transplant. Participants needed to have stable graft function (as determined by their physician; typically defined as a serum creatinine within 20% of baseline) and agree to participate for the 12-month trial duration. The exclusion criteria were a body mass index (BMI) > 40 kg/m^2 or <18.5 kg/m^2, significant malnutrition (requiring enteral/parenteral nutrition therapy), or ongoing significant medical complications, as determined by the physician.

All participants were cared for by the regional transplant center for the first 2 months after transplant. From month 3 onwards, routine transplant care reverted to the local hospital renal unit. Participants attended the transplant center for study visits. Reimbursement was offered for transport costs; study visits were flexible and were scheduled alongside medical appointments whenever possible.

Randomization and Blinding

Participants were randomly assigned 1:1 to the intensive nutrition intervention or standard care, using a computer-generated sequence allocation with variable size permuted blocks, stratified by gender. Allocation concealment was via sealed opaque envelopes. Outcome assessments (weight, anthropometry, body composition, and physical function) were performed by an investigator blinded to the group allocations.

Nature of Nutrition Care

Nutrition care offered to transplant patients, and utilized in this trial, follows the Nutrition Care Process developed by the Academy of Nutrition and Dietetics (Chicago, USA). This is a standardized process of care which involves nutrition assessment, diagnosis, intervention, monitoring, and evaluation.[28] Nutrition recommendations followed guidelines for transplant recipients; further details of the specific recommendations are described in Table 1 of the Appendix: Supplementary Methods.[12,29,30]

Control Group: Standard Care

Participants randomized to standard care received post-transplant care as per usual local practice. Standard immunosuppression included a calcineurin inhibitor (cyclosporine or tacrolimus), mycophenolate, steroids, and basiliximab as induction therapy. Standard nutrition care after transplant includes a consultation with a renal dietitian during the inpatient stay (to provide food safety and healthy eating advice) and up to 3 further consultations to manage nutrition problems at 1, 3, and 12 months after transplant, alongside regular physician appointments. A single dietitian was assigned to provide consultations for the standard care group during the trial.

Intervention Group: Intensive Nutrition Intervention

Participants randomized to the intervention group received, in addition to standard care, 8 additional consultations with a renal dietitian, that is, a total of 12 visits over 12 months. Consultations were offered fortnightly between months 1 and 3, monthly between months 4 and 6, and bimonthly between months 7 and 12. Self-administered 3-day food diary records were completed before reviews at 1, 3, 6, and 12 months and were analyzed using FoodWorks® Professional software.

Individualized nutrition counselling was provided using motivational interviewing techniques to increase patient engagement and facilitate behavior change. Personalized action plans were developed which involved setting S.M.A.R.T. (specific, measurable, achievable, relevant, and time-bound) patient-centered goals.[31] At each review session, the dietitian assessed progress with nutrition interventions and goals. Up to 3 dietitians were involved in conducting consultations during the trial; participants remained with the same dietitian throughout the study wherever possible.

In addition, intervention group participants received tailored physical activity and exercise advice from an exercise physiologist at 2, 3, and 6 months after transplant. The advice took into consideration the participants' attitude toward physical activity and their past and present exercise level (see the Appendix: Supplementary Methods for further details).

Primary and Secondary Outcomes

The primary outcome was body weight at 6 months after transplant, adjusted for baseline weight, obesity (BMI ≥ 30 kg/m^2), and gender. Weight was measured after an overnight fast using calibrated electronic scales and recorded to the nearest 0.1 kg.

The secondary outcomes included changes in weight and other anthropometric measures, body composition, resting energy expenditure, physical function measures, physical activity, serum biochemistry, and quality of life (QOL) at 3, 6, and 12 months after transplantation.

Data Collection

Study assessments were undertaken at baseline (1 month), 3, 6, and 12 months after transplant. Routine demographic, clinical, and laboratory data were recorded, including details of any acute medical problems, adverse events, graft function, hospital admissions, medications, or other factors that might affect nutritional status or weight.

Participants fasted overnight before the study assessments, which were conducted at the University of Auckland Body Composition Laboratory. The measures listed in the following sections were collected (see Appendix: Supplementary Methods for full details).

Anthropometry

Body weight, BMI, waist circumference and waist-hip ratio, midarm circumference, and skin-fold thickness were measured using standardized methods on calibrated instruments. Weight was obtained from clinical records for participants who withdrew from the study. The same

investigator performed the measurements for all participants, was blinded to group allocations, and used the same equipment to ensure standardization.

Body Composition, Resting Energy Expenditure

Dual-energy X-ray absorptiometry (DXA) was used to determine total body fat, percent fat, fat-free mass, and abdominal fat and derive measures of abdominal visceral fat and subcutaneous fat. Total body nitrogen was measured using prompt gamma in vivo neutron activation analysis.[32] Total body protein was calculated as 6.25 × total body nitrogen. Total body potassium measurements were taken with a whole body counter, which measures radioactivity of the body due to ^{40}K.[33] Open-circuit indirect calorimetry was used to determine resting energy expenditure.

Physical Function and Physical Activity

Physical function was assessed using maximal grip strength in the dominant hand using a dynamometer, gait speed over 7.62 m (25 feet), and a sit-to-stand-to-sit test.[34] Physical activity was assessed using the short form of the New Zealand Physical Activity Questionnaire.[35]

Nutritional Status

Nutritional status was assessed by the dietitian using the patient-generated subjective global assessment.[36]

Biochemistry

Blood samples were collected and assayed for glucose, HbA1c, insulin, lipids (total, low-density lipoprotein [LDL] and high-density lipoprotein [HDL] cholesterol, and triglycerides). Insulin resistance was calculated using the computer-based homeostatic model assessment.[37]

Quality of Life

QOL was assessed using the Short Form-36 (SF-36®)[38] and was compared at 12 months with New Zealand norms.[39]

Statistical Analysis

The primary outcome (body weight at 6 months after transplant) was analyzed by intention to treat, using an analysis of covariance (ANCOVA) adjusted for baseline weight, obesity (BMI ≥30 kg/m^2), and gender. For secondary outcomes, changes were analyzed with repeated measures using linear mixed models, which can accommodate missing data, and group, time, and group × time effects reported. Comparisons between groups were conducted using Fisher's exact test for categorical variables, unpaired t tests for parametric variables, and Wilcoxon rank-sum tests for nonparametric variables. Statistical analysis was performed using SAS release 9.4 (SAS Institute, Cary, NC), and $P < .05$ was considered as statistically significant. Data are expressed as mean ± standard deviation (SD) or standard error, as stated.

Sample Size Estimation

We aimed to recruit 32 participants (16 in each group) to have 80% power and type 1 error of 5% to detect a clinically important 5 kg difference in weight at 6 months in the ANCOVA analysis: (69 ± [SD] 12 kg vs. 74 ± 9 kg), allowing for a dropout rate of 12.5%, that is, a minimum sample of 28 participants who received the interventions. These estimates were based on data from a previous nonrandomized study of nutrition intervention in the first year after transplant.[26] The correlation between baseline and 6-month weight was estimated to be 0.9, based on the local data for these values (correlation of 0.9515 for 1,299 Auckland renal transplant recipients from 1991 to 2012; unpublished observations).

Results

Participants

Between March 2014 and July 2015, 111 kidney transplants were performed, and 60 patients met the eligibility criteria. Thirty-seven participants enrolled in the trial; 19 were randomized to the intervention group and 18 to the control group. One participant withdrew on medical grounds before the baseline assessment and was excluded. Figure 2 shows the trial CONSORT diagram. Ten participants (28%, 5 each group) withdrew during follow-up (Table S1). Withdrawals tended to occur earlier in the intervention group. Body weight was obtained for all 36 participants. Of those who completed the study (n = 26), participants in the intervention group attended 134 of 143 scheduled appointments (93%), and participants in the standard care group attended 38 of 39 (97%) scheduled appointments.

Participant baseline characteristics are shown in Table 1.

Primary Outcome: Weight

In the primary outcome ANCOVA analysis, weight at 6 months did not differ significantly between the groups (intervention: 77.0 ± SD 12.4 kg; control: 82.2 ± 13.4 kg, difference in adjusted means 0.4 kg, 95% confidence interval −2.2 to 3.0 kg; $P = .7$). A "per-protocol" analysis of the 26 participants who completed the study similarly did not show any difference between the groups (Table 2).

Secondary Outcomes

Over 12 months, the mean body weight increased (baseline: 78.0 ± 13.7 [SD] kg; 6 months: 79.6 ± 13.0 kg; 12 months: 81.6 ± 12.6 kg, $P < .001$), a mean increase of 4.6% (Table 2 and Fig. 3).

Results for anthropometry, body composition, and resting energy expenditure are shown in Table 3; physical function and physical activity are shown in Table 4. Results for biochemistry, QOL, and dietary intake are shown in Tables S1-S3, respectively.

Body Composition and Energy Expenditure

Over the 12-month period, group × time interaction effects were not significant for BMI,

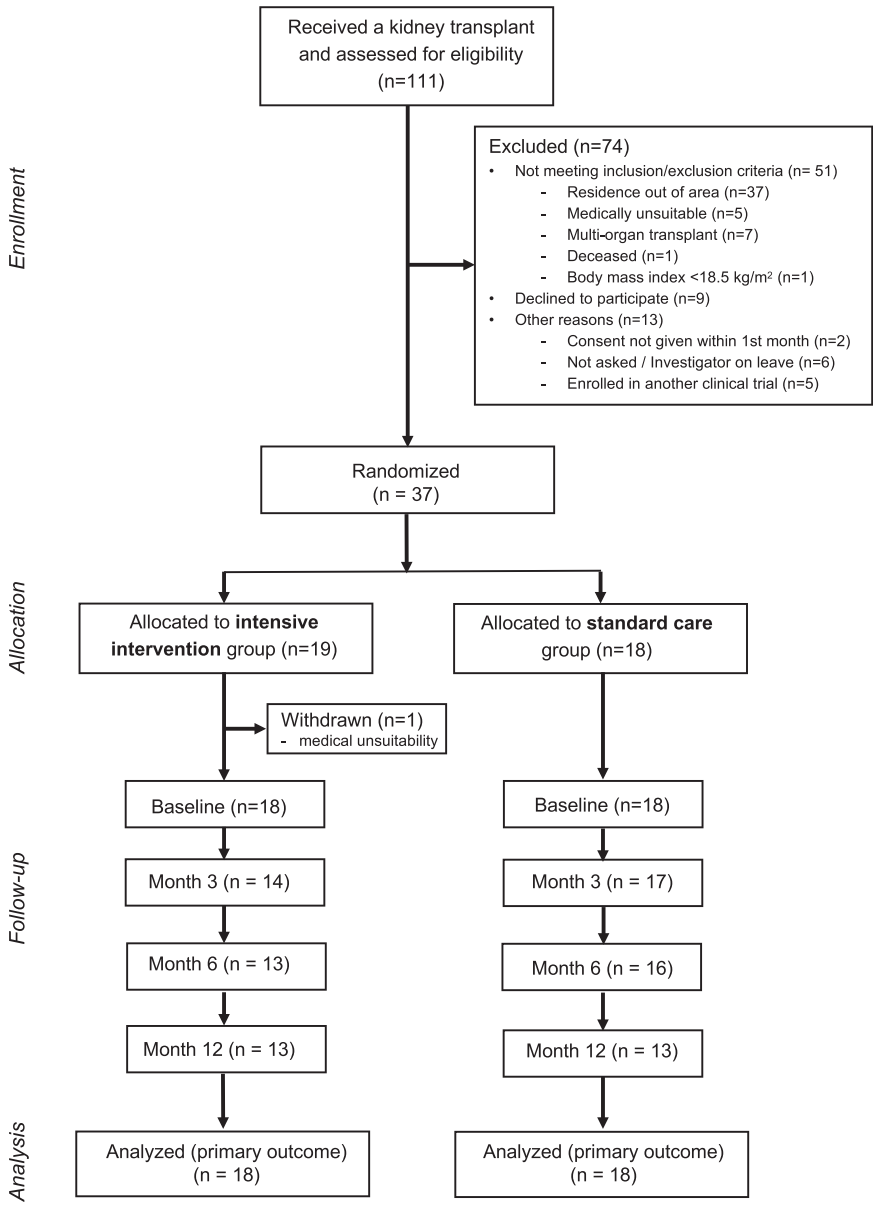

Figure 2. The INTENT trial Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

anthropometry, body composition by DXA, total body protein, total body potassium, and resting energy expenditure (Table 3).

However, in the cohort as a whole, total body fat ($P = .003$), percent body fat ($P = .008$), and abdominal fat ($P = .001$) all increased, including both visceral and subcutaneous compartments (both $P = .009$). Over time, there was a trend for fat-free mass ($P = .06$), with a tendency for average fat-free mass to increase over the final 6 months of the study. Total body protein ($P = .008$) and total body potassium ($P = .03$) also increased over time. Resting energy expenditure did not significantly change over the 12-month study period.

Physical Function

There were no significant differences between groups over time in grip strength, gait speed, or sit-to-stand-to-sit test (Table 4). For the whole cohort, grip strength and gait speed increased over the 12 months ($P = .001$) and sit-to-stand-to-sit time decreased ($P < .001$). Reported physical activity did not differ between the groups but increased overall ($P < .001$).

Biochemistry

There were no significant differences between the groups in any of these parameters (Table S2). Over the whole cohort, HbA1c ($P = .01$) and fasting glucose

Table 1. Baseline Characteristics of the INTENT Trial Participants

Variable	Standard Care	Intervention
No. of participants	18	18
Age (y)	48.3 (±13.9)	49.2 (±14.6)
Gender		
Female, n (%)	5 (28)	6 (33)
Male, n (%)	13 (72)	12 (67)
Anthropometry		
Weight (kg)	81.1 (±13.9)	74.8 (±13.1)
Height (cm)	171.7 (±6.4)	172.0 (±8.2)
BMI (kg/m^2)	27.5 (±4.2)	25.2 (±3.9)
Obese, n (%)	5 (28)	1 (6)
Overweight, n (%)	8 (44)	7 (39)
Causes of CKD		
Glomerulonephritis	10 (56)	10 (56)
Polycystic kidney disease	0	1 (5)
Diabetic nephropathy	5 (28)	3 (17)
Other	3 (17)	4 (22)
Type of dialysis		
HD, n (%)	10 (56)	11 (61)
PD, n (%)	3 (17)	3 (17)
HD and PD, n (%)	2 (11)	2 (11)
No dialysis, n (%)	3 (17)	2 (11)
Mean duration of dialysis (mo)	45.5 (33.2)	50.5 (45.2)
Type of transplant donor		
Live, n (%)	7 (39)	6 (33)
Deceased, n (%)	11 (61)	12 (67)
No. of previous kidney transplants		
No previous transplants, n (%)	18 (100)	14 (78)
One previous transplant, n (%)	0	4 (22)
Immunosuppressive medication		
Cyclosporin (baseline/12 mo)	14/9	13/9
Tacrolimus (baseline/12 mo)	4/9	5/9
CVD risk factors		
History of CVD, n (%)	6 (33)	9 (50)
History of HTN, n (%)	13 (72)	15 (83)
History of dyslipidemia, n (%)	6 (33)	7 (39)
Current smoker, n (%)	1 (6)	0
Diabetes, n (%)	6 (33)	3 (17)

BMI, body mass index; CKD, chronic kidney disease; CVD, cardiovascular disease; DXA, dual-energy X-ray absorptiometry; HD, hemodialysis; HTN, hypertension; PD, peritoneal dialysis.

Data are given as number of patients (percentage) or mean ± standard deviation.

($P = .004$) increased, but LDL ($P = .02$), triglycerides ($P = .04$), and total cholesterol ($P = .007$) decreased. Five participants (2 control; 3 intervention) developed new-onset diabetes after transplant. Creatinine decreased significantly in both groups over time ($P = .005$). There were no time or group effects seen for insulin resistance.

Quality of Life

For the domain "general health," a significant interaction effect was seen ($P = .03$) where, between 6 and 12 months, improvement resulted for the control group ($P = .003$) but not for the intervention group ($P = .3$). No statistically significant interaction effects were found for the remaining 7 domains (Table S3). Over 12 months, physical functioning ($P = .003$), role physical ($P < .001$), bodily pain ($P < .001$), vitality ($P < .001$), social functioning ($P < .001$), role emotional ($P < .001$), and mental health ($P = .05$) significantly improved for the entire cohort.

Comparison of 12-month results to population norms showed no significant differences in physical functioning, role physical, bodily pain, general health, and vitality; the INTENT participants reported higher scores in the domains role emotional ($P < .001$) and mental health ($P < .001$).

Nutrient Intake

Total energy intake in the intervention group decreased from baseline to 6 months, before increasing almost back to the baseline level at 12 months ($P = .02$, Table S4). However, among intervention group participants who completed the trial, 6 were suspected of intentional or unintentional under-reporting for at least one of the food diaries they provided (see Appendix: Supplementary Methods; data not shown). There were no statistically significant differences for other macronutrients or relevant micronutrients between baseline and 12 months. Participants met recommended levels for higher protein intake in the acute phase (baseline); however, the intake remained high and was above recommendations during the trial.[30] Fat intake was within the recommended 30%-35% of total energy from 3 to 12 months. Average sodium consumption at 12 months was within the recommended range of 1,850-2,300 mg/day. Recommended intakes for saturated fat, fiber, and calcium were not consistently met. Nutritional intake data were not collected from standard care participants.

Adverse Events and Unplanned Hospital Admissions

There were no adverse events attributed to trial participation. Two intervention group participants had suspected malnutrition at baseline by patient-generated subjective global assessment. Another intervention group participant developed suspected malnutrition at 6 months following hospitalizations.

There were a significant number of unplanned hospital admissions among participants: 38 admissions (median 2.5 days, range 0-43) in the intervention group, compared with 21 in the control group (median 1 day, range 0-54) ($P = .4$). Six participants had hospital stays of >7 days; 2 in control; 4 in intervention (1 intervention participant withdrew).

Discussion

To our knowledge, this is the first RCT of an intensive nutrition intervention in the first year after kidney transplantation. There was no difference in weight at 6 months and therefore no additional benefit of the intensive intervention, compared with guideline-based standard nutrition care. By delivering an intervention in the early period after transplant, our hypothesis was that this could avoid the adverse changes in body composition and weight that

Table 2. Body Weight

Measurement	Baseline	3 mo	6 mo	12 mo	*P*		
					Group	Time	Group × Time
Intention-to-treat analysis (n = 36)							
Body weight (kg)							
STD	81.1 (±13.9)	82.5 (±14.4)	82.2 (±13.4)	83.6 (±13.4)	.220	<.001	.374
INT	74.8 (±13.1)	76.3 (±13.5)	77.0 (±12.4)	79.7 (±12.5)			
Weight difference compared to baseline (kg)							
STD		1.4 (±2.4)	1.1 (±3.4)	2.5 (±4.0)			
INT		1.2 (±2.5)	2.2 (±3.6)	4.9 (±5.9)			
Body weight (kg) for both the STD and INT groups combined							
	78.0 (±13.7)	79.4 (±14.1)	79.6 (±13.0)	81.6 (±12.9)			
Per-protocol analysis (n = 26)							
Body weight (kg)							
STD	76.8 (±11.4)	78.4 (±11.1)	78.7 (±11.6)	80.3 (±12.4)	.561	.002	.718
INT	74.2 (±15.3)	74.7 (±15.0)	75.6 (±14.3)	77.5 (±13.9)			
Weight difference compared to baseline (kg)							
STD		1.6 (±2.3)	1.9 (±3.4)	3.5 (±4.0)			
INT		0.5 (±2.2)	1.4 (±3.4)	3.2 (±4.8)			

INT, intensive intervention group; STD, standard care.
Values are expressed as mean ± standard deviation.

frequently occur. While this study demonstrates the safety and feasibility of delivering the intervention in this setting, our data do not currently justify a larger multicenter trial of an intensive nutrition intervention to improve long-term clinical outcomes.

Weight increased significantly, albeit modestly (<5%), at 6 and 12 months; this differs from findings in many previous studies where weight gains were greater (10% or more) and suggests that both groups may have derived benefit from receiving the trial interventions. A nonrandomized comparative study conducted over a similar time period after transplant reported greater weight gain after 4 months in both the intervention and control (no nutrition care) groups, although there was a significant advantage reported for the intervention.[26] The one prior RCT of a nutrition intervention after transplant conducted in participants with impaired glucose tolerance (mean 5.4 years after transplant) did not find significant changes in body weight or anthropometry.[40] The relatively small mean weight gain observed in both INTENT groups might have reduced the ability of the intervention to show an effect. This could be due to bias from the so-called "Hawthorne effect," that is, participants in both groups altering behavior solely because of their participation in a research study.[41] Alternatively, even the less rigorous approach used in standard care may be sufficiently effective for participants to become more aware of their dietary intake and alter their behavior as a result. We did not include a group that received no nutrition care (this was not considered ethical in our setting where standard nutrition care is provided to all patients), and thus, we cannot determine whether such a group would have experienced greater adverse changes in weight and body composition than the participants in this study.

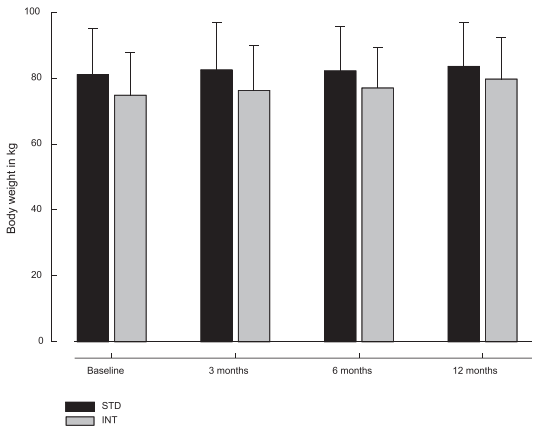

Figure 3. Body weight for participants who received standard care (STD) and those who received intensive nutrition intervention (INT). Data are expressed as mean ± standard deviation.

Resting energy expenditure did not differ significantly between the groups or over time, and therefore, this could not explain the observed weight gain. However, total reported energy intake in the intervention group decreased between baseline and 6 months, before returning to baseline levels at 12 months. Given the lack of change in measured resting energy expenditure, the reported energy intake should not have resulted in significant weight gain, especially as physical activity increased over time. These results suggest potential participant under-reporting by 6 intervention participants for at least one of the food diaries they provided. To detect potential under-reporting, a physical activity level of ≤1.2 was used that is thought to correlate to individuals who are exclusively sedentary, chair- or bed-bound; this threshold was thus likely conservative.[42] While food diaries are considered more

Table 3. Anthropometry and Body Composition

Measurement	Baseline	3 mo	6 mo	12 mo	*P*		
					Group	Time	Group × Time
BMI (kg/m^2)							
STD	27.5 (±1.0)	28.0 (±1.6)	27.9 (±1.0)	28.3 (±1.0)	.152	<.001	.354
INT	25.2 (±0.9)	25.7 (±1.0)	26.0 (±0.9)	26.9 (±0.9)			
Waist circumference (cm)							
STD	101.2 (±2.7)	101.2 (±2.7)	96.6 (±2.6)	99.9 (±2.7)	.126	.219	.484
INT	94.5 (±6.0)	92.8 (±3.9)	93.5 (±3.7)	96.0 (±3.5)			
Hip circumference (cm)							
STD	103.3 (±1.8)	103.9 (±2.2)	102.5 (±2.5)	102.6 (±2.3)	.242	.086	.608
INT	100.0 (±1.6)	99.8 (±2.3)	99.2 (±2.2)	101.9 (±1.8)			
Waist-hip ratio							
STD	0.98 (±0.0)	0.98 (±0.0)	0.95 (±0.0)	0.97 (±0.0)	.284	.919	.572
INT	0.94 (±0.0)	0.93 (±0.0)	0.94 (±0.0)	0.94 (±0.0)			
Midarm circumference (cm)							
STD	32.0 (±1.0)	32.1 (±1.0)	31.9 (±0.8)	32.2 (±1.0)	.268	.046	.528
INT	31.3 (±1.2)	29.8 (±0.9)	29.9 (±0.8)	31.0 (±1.0)			
Triceps skinfold (mm)							
STD	20.0 (±3.6)	18.3 (±1.8)	18.7 (±2.0)	21.2 (±2.8)	.521	.076	.700
INT	17.9 (±2.9)	13.9 (±1.2)	15.1 (±1.7)	17.5 (±2.2)			
Biceps skinfold (mm)							
STD	10.0 (±1.7)	11.3 (±2.4)	11.0 (±1.7)	13.2 (±3.3)	.350	.002	.140
INT	9.3 (±1.7)	6.3 (±0.7)	10.0 (±1.5)	7.8 (±1.3)			
Corrected midarm muscle area (cm^2)							
STD	44.6 (±3.3)	47.0 (±2.9)	45.7 (±2.5)	43.3 (±2.7)	.710	.793	.837
INT	45.2 (±4.4)	43.3 (±3.6)	41.9 (±3.2)	43.3 (±3.8)			
Total muscle mass by anthropometry (kg)							
STD	26.7 (±1.7)	27.9 (±1.6)	27.2 (±1.3)	26.1 (±1.4)	.864	.797	.835
INT	27.5 (±2.5)	26.4 (±2.0)	25.7 (±1.8)	26.6 (±2.1)			
Total body fat % by skinfold							
STD	31.2 (±1.8)	32.6 (±2.0)	32.7 (±1.8)	34.0 (±1.7)	.390	<.001	.243
INT	30.5 (±1.7)	28.4 (±1.2)	31.3 (±1.9)	31.3 (±1.8)			
Total body fat by DXA (kg)							
STD	27.7 (±2.2)	28.9 (±2.6)	27.7 (±2.3)	29.1 (±2.8)	.125	.003	.697
INT	23.8 (±2.0)	22.3 (±1.9)	22.9 (±1.8)	24.9 (±1.9)			
Total body fat % by DXA							
STD	33.5 (±1.8)	35.2 (±2.1)	34.4 (±2.0)	35.4 (±2.2)	.296	.008	.580
INT	31.6 (±1.8)	30.2 (±1.6)	30.8 (±1.4)	31.9 (±1.5)			
Fat-free mass by DXA (kg)							
STD	54.0 (±1.7)	52.3 (±1.8)	52.1 (±1.4)	52.1 (±1.7)	.478	.056	.084
INT	51.0 (±2.4)	51.9 (±2.6)	51.5 (±2.6)	53.4 (±2.8)			
Bone mineral content by DXA (kg)							
STD	2.8 (±0.1)	2.8 (±0.1)	2.7 (±0.1)	2.7 (±0.1)	.750	.677	.373
INT	2.6 (±0.2)	2.7 (±0.2)	2.7 (±0.2)	2.8 (±0.2)			
Abdominal fat by DXA (kg)							
STD	2.8 (±0.3)	2.9 (±0.3)	2.8 (±0.3)	2.9 (±0.3)	.093	.001	.959
INT	2.2 (±0.3)	2.2 (±0.3)	2.1 (±0.2)	2.5 (±0.3)			
Visceral fat by DXA (kg)							
STD	1.5 (±0.2)	1.5 (±0.2)	1.4 (±0.2)	1.4 (±0.2)	.407	.009	.576
INT	1.2 (±0.2)	1.4 (±0.3)	1.3 (±0.2)	1.5 (±0.3)			
Visceral fat % by DXA							
STD	20.9 (±2.3)	21.3 (±2.5)	21.0 (±2.2)	20.3 (±2.9)	.604	.165	.547
INT	18.5 (±2.9)	20.8 (±3.7)	20.7 (±3.4)	21.5 (±3.7)			
Subcutaneous fat (kg)							
STD	1.3 (±0.2)	1.4 (±0.2)	1.4 (±0.2)	1.5 (±0.2)	.059	.009	.502
INT	1.0 (±0.1)	0.9 (±0.1)	0.9 (±0.1)	1.0 (±0.1)			
Total body protein (kg)							
STD	11.2 (±0.4)	11.1 (±0.5)	11.3 (±0.5)	11.4 (±0.5)	.854	.008	.861
INT	11.0 (±0.4)	11.2 (±0.5)	11.2 (±0.6)	12.0 (±0.6)			
Total body potassium (mmol)							
STD	3,020 (±92)	3,079 (±108)	3,013 (±111)	3,078 (±101)	.700	.031	.175
INT	2,861 (±158)	2,971 (±173)	2,997 (±146)	3,180 (±147)			

(*Continued*)

Table 3. Anthropometry and Body Composition (*Continued*)

					P		
Measurement	Baseline	3 mo	6 mo	12 mo	Group	Time	Group × Time
REE (kcal/d)							
STD	1,439 (±42)	1,442 (±53)	1,404 (±61)	1,412 (±41)	.372	.411	.260
INT	1,335 (±56)	1,356 (±54)	1,414 (±66)	1,401 (±45)			

BMI, body mass index; DXA, dual-energy X-ray absorptiometry; INT, intensive intervention group; REE, resting energy expenditure; STD, standard care.

Values are expressed as mean ± standard error of the mean.

accurate compared to other methods (24-hour recall and diet histories), intentional and unintentional under-reporting is common, and estimating amounts can result in inaccuracies.[43]

Similar to the findings for weight, no significant differences were seen between the groups for a range of body composition measures. Overall, total body fat mass significantly increased, as reported in previous studies. This was partially explained by significant increases in abdominal, visceral and subcutaneous adipose tissue over time. Abdominal obesity and particularly visceral adipose tissue is strongly linked to the development of metabolic syndrome, insulin resistance, type 2 diabetes, and ultimately CVD.[44,45] There remains an unmet need for interventions in transplant recipients that can target these adverse metabolic changes.

Physical function measures improved significantly over time across the groups, as did the amount of physical activity reported by participants. Combined with dietary management, physical activity has been shown to have beneficial long-term effects on weight.[46] In kidney transplant recipients, low levels of physical activity have also been associated with weight gain and mortality.[8,47] Intervention group participants met with an exercise physiologist in this trial; however, this did not result in significantly more time spent physically active. Although a more structured approach to increase physical activity and exercise training in transplant recipients is often considered more effective in achieving weight loss or improving cardiovascular outcomes, such approaches are not currently supported by evidence from RCTs in transplant recipients.[48] It is therefore of considerable interest that there is a multicenter trial in renal transplant recipients investigating exercise training with or without concurrent dietitian nutritional intervention underway in the Netherlands, with the aim of improving patient-reported physical function and other measures.[49]

In parallel with the observed weight gain in both groups, HbA1c and fasting glucose significantly increased, and at 12 months, values for HbA1c remained elevated at levels indicative of impaired glucose tolerance. Previous larger studies have, however, reported improved glucose tolerance through nutrition interventions, although weight loss was also reported.[25] In contrast, significant improvements were detected in LDL and total cholesterol across the entire cohort. These findings are in line with previously reported improvements in blood lipid levels following nutrition intervention.[25,40] However, we were not able to adjust for the variable use of lipid-lowering drugs (eg, statins) over time in this analysis, and therefore, it is not possible to determine the extent to which these changes were due to drug effects rather than dietary changes.

Table 4. Physical Function and Physical Activity

					P		
Variable	Baseline	3 mo	6 mo	12 mo	Group	Time	Group × Time
Grip strength (kg)							
STD	36.5 (±1.7)	36.5 (±2.0)	38.7 (±2.0)	40.1 (±1.9)	.706	.001	.986
INT	35.2 (±2.8)	36.6 (±3.7)	36.0 (±3.8)	37.8 (±3.5)			
Gait speed (m/s)							
STD	2.0 (±0.1)	2.3 (±0.1)	2.5 (±0.1)	2.5 (±0.1)	.447	.001	.304
INT	2.3 (±0.2)	2.4 (±0.2)	2.4 (±0.2)	2.6 (±0.3)			
Sit-to-stand-to-sit test (s)							
STD	20.4 (±1.6)	17.7 (±1.2)	16.4 (±1.2)	14.5 (±1.4)	.892	<.001	.167
INT	21.9 (±2.8)	18.2 (±2.5)	15.1 (±1.4)	15.0 (±1.8)			
Physical activity (min/wk)*							
STD	100.0 (0-434)	150.0 (0-340)	180.0 (0-465)	180.0 (0-420)	.782	<.001	.602
INT	59.5 (0-360)	200.0 (0-810)	215.0 (0-550)	340.0 (60-525)			

INT, intensive intervention group; STD, standard care.

Values are expressed as mean ± standard error of the mean or median (range).

*Mixed model analysis was carried out on ranked data.

QOL improved overall as expected; compared to dialysis, transplantation is associated with significantly better QOL which is sustained over time.[50] For the domain "general health," control participants scored higher than intervention participants at 12 months. The intervention group participants had collectively more unplanned hospital admissions, which might explain these differences. No differences in other domains were seen. Compared with New Zealand normative data, the combined scores for all INTENT participants at 12 months were similar or better than the general population. The reason for higher QOL scores for "role emotional" and "mental health" are unknown, although we postulate that some improvements could be due to a "contrast" effect; that is, QOL may be perceived more positively among transplant recipients for some domains due to the significant increase in well-being that occurs after successful transplantation.[50]

The major strength of the INTENT trial was the use of a robust, randomized, single-blind design. While it was not possible to blind participants or treating physicians, the outcomes assessor was blinded to group allocations. The same investigator performed all formal body composition measurements with the same instruments to reduce the possibility of measurement variability and therefore confounding.

Another key strength of this trial was the use of gold-standard body composition measurements. The combined use of in vivo neutron activation analysis, whole-body counting for total body potassium, DXA, and indirect calorimetry in an intervention trial of transplant recipients is unique and increases the detail of our findings.

Participants in the INTENT trial represented approximately 60% of the eligible transplant cohort transplanted during the time period and are broadly representative of the population of transplant recipients. Trial participants had a similar prevalence of comorbidities and baseline characteristics to those in transplant populations elsewhere.[51]

The main limitations of the INTENT trial are the relatively small sample size, and the single-center design. One of our objectives was to show proof-of-concept for the efficacy of the intervention that could provide a basis to conduct a larger multicenter trial powered to a more clinically relevant outcome.[27] We used estimates of effect size and weight variability derived from the only previous study conducted in a similar setting.[26] We used a 6-month primary outcome measure expected to be sensitive for treatment effects: significant weight gain is expected by this time after transplant and previous studies showed benefits after interventions of a similar duration. The potential for imbalance between groups with a small sample size was accounted for by using an ANCOVA primary analysis adjusted for important baseline variables (weight, obesity, and gender).

The attrition rate was 28%, which was higher than anticipated; given this, recruitment was extended to maintain power. Withdrawals were equal in both groups; intervention participants tended to request withdrawal earlier than control participants, and the most commonly cited reason in both groups was work commitments. Travel times may have been a factor, as 80% of those who withdrew were resident in another hospital catchment away from the transplant center. While a reasonably high rate of hospitalization was noted, this is not necessarily unexpected during the first year after transplant.[52] The reasons for admissions varied, although investigation of graft dysfunction or treatment of urinary tract infections were the frequent causes; reported hospitalizations also included elective admissions for procedures (eg, fistula excision or hernia repair). Other than prolonged hospitalizations (>7 days; n = 6 participants, 1 withdrawal), most of these admissions had a minimal impact on study participation.

Owing to the nature of post-transplant care, preventing trial participants from interacting with each other in the outpatient clinic was not possible. At our center, transplant recipients initially attend clinics daily, tapering to fortnightly over 6 months. During this period, participants likely had frequent incidental contact with each other. This could have enabled control group participants to find out details of the nutrition and exercise advice provided to intervention group participants. This is a potential limitation of any trial involving counselling-based interventions in a transplant population provided in a clinic setting.

The nutrition care provided to the participants in this trial involved dietetic resources that may not be available at all centers.[53] Future studies of nutrition interventions need to consider strategies to address these resource issues, such as telehealth or other innovative approaches to care delivery,[54] to ensure that results can be generalized to the wide range of settings where post-transplant care is provided. Similarly, the ability to deliver interventions closer to the participant's place of residence might improve rates of adherence and reduce attrition rates.

In conclusion, the INTENT trial did not demonstrate any advantage for an intensive nutrition and exercise intervention over standard nutrition care in the first year after transplant. However, our findings suggest that standard nutrition care delivered by dietitians, including monitoring every 3 months, is associated with relatively modest increases in weight and body fat, compared to historically reported outcomes. Although our hypothesis was not proven, INTENT represents an important development in transplant clinical nutrition research and will inform the design of future studies. Further studies are needed to determine the optimal approach to avoid the adverse consequences of weight gain after transplant.

Practical Application

Kidney transplant recipients frequently gain a lot of weight after transplant, especially in the first year, but it is unknown whether nutrition interventions can help patients avoid excessive post-transplant weight gain. In this RCT, an intensive nutrition intervention did not reduce weight gain compared with standard nutrition care, although trial participants did not gain as much weight as expected. Standard nutrition care may therefore be beneficial, but further studies are needed to prove this and determine the best approach to prevent weight gain after kidney transplantation.

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Supplementary Data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1053/j.jrn.2018.03.001.

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