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

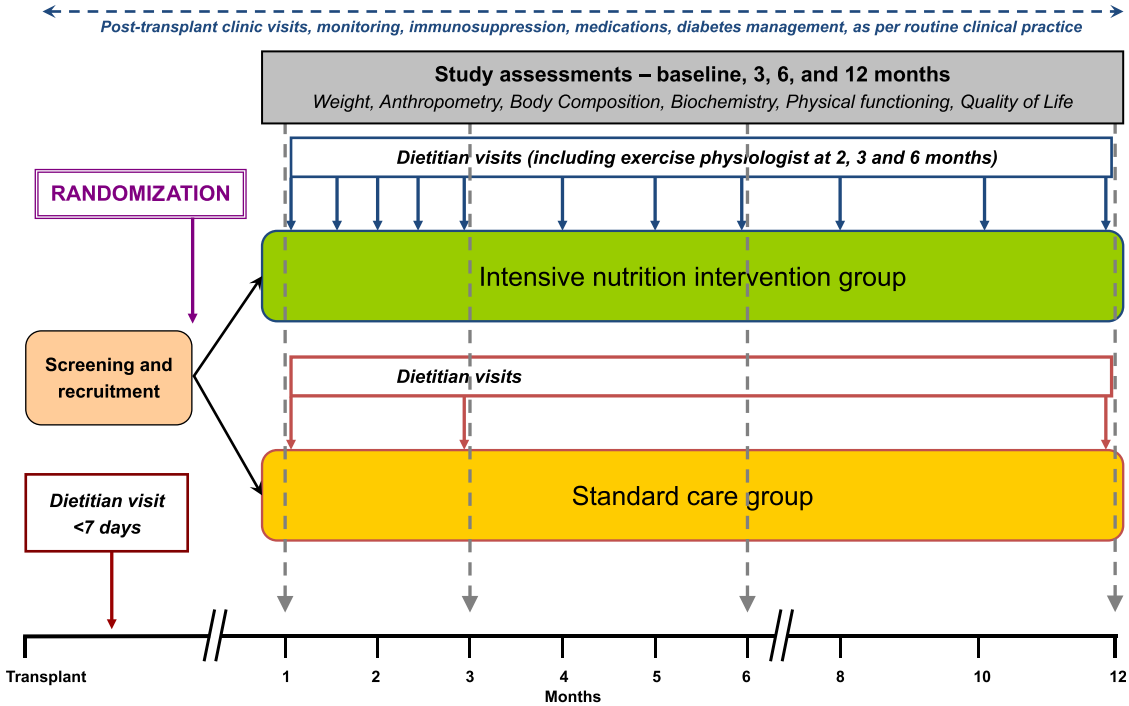

Figure 1. Study design and flowchart. Ryan et al. (2014)[27]