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Comparison of a Behavioral Versus an Educational Weight Management Intervention After Renal Transplantation: A Randomized Controlled Trial

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Background. In the first year following renal transplantation, preventing weight gain to minimize overweight or obesity is particularly important. The aim of this study is to test the effect of an 8-month behavioral intervention BMI and physical activity. **Methods.** This randomized controlled study included 123 adult kidney or kidney-pancreas recipients. Patients were randomized to usual (1 educational session, then weight self-monitoring) and intervention care (usual care plus 7–8 counseling sessions). Alongside weight, body composition, and physical activity, satisfaction and perceptions regarding care were measured at weeks 2–6 (baseline), then at months 8 and 12. **Results.** Both groups reported comparably high satisfaction. The intervention group (IG) reported more chronic care-related activities. In patients with BMIs ≥ 18.5, mean weight gain (from baseline) was unexpectedly low in both groups: at month 8, +0.04 kg/m^2 in IG patients and +0.14 kg/m^2 in the control group (P = 0.590), and respectively, +0.03 kg/m^2 and +0.19 kg/m^2 at month 12 (P = 0.454). Both groups were physically active, walking averages of 10 807 (IG) and 11 093 (control group) steps per day at month 8 (P = 0.823), and respectively 9773 and 11 217 at month 12 (P = 0.195). **Conclusions.** The behavioral intervention had high patient acceptance and supported patients in maintaining their weight, but had no superior effect on a single educational session. Further research is needed to assess patient weight gain risk profiles to stratify the intervention.

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In spite of its many benefits, kidney transplantation is also linked to a range of comorbidities, including cardiovascular disease and diabetes,[1] that are exacerbated by overweight (BMI 25.00–29.99) or obesity (BMI ≥30). Unfortunately, many kidney failure patients have trouble managing their weight. Even in the first year following renal transplantation, weight gain is common: internationally, mean country-level increases range from 1.9[2] to 5.7 kg.[3,4] A survey in a large Swiss cohort showed that the percentage of recipients with normal weight decreased from 42.9% to 39.6% within the first 3 years

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posttransplantation, whereas the prevalence of overweight (BMI ≥25) increased from 34.6% to 37.3% and of obesity from 19.3% to 20.9%[2]—double that of the normal Swiss population.[5] As patients with normal weight commonly shift to overweight and obesity over a 3-year period, prevention of weight gain is relevant to all patients regardless of their baseline BMI.

Compared with normal weight (BMI 18.5–24.9)[6-8] or otherwise nonobese renal transplant recipients (BMI <30),[9] recent findings indicate that obese renal transplant recipients have increased mortality rates[6,7] due to cardiovascular disease,[9] delayed graft function,[7-9] acute rejection,[7] and allograft loss.[7,8] While reports disagree on the consistency of correlations between obesity and mortality[8,9] or acute rejection,[9] weight gain—particularly if it is rapid—in the first year posttransplant remains strongly associated with poor clinical outcomes—regardless of baseline BMI. For example, rapid first-year weight gain of 20% correlates with an increased risk of death,[10] rapid increases in BMI correlate with higher risks of new onset diabetes,[11] and a BMI increase above 5% correlates with graft loss.[12] Therefore, establishing a healthy diet and routine physical activity is especially important in the immediate posttransplant period. This is the case for patients with normal weight as well as for patients with overweight or obesity.

Despite the relevance of weight gain and physical activity on posttransplant outcomes, the implementation of weight management interventions in posttransplant care varies widely in regard to dose (none, single versus various), length (once versus y posttransplant), content (topics), and method (educational versus behavioral).[13,14] Current guidelines recommend structured programs for patients with obesity and not further defined encouragement of healthy lifestyle in all patients.[15] While single educational sessions are well received in practice, the implementation of complex lifestyle interventions in clinical practice faces various barriers, of which lack of resources, lack of feasibility, or low uptake by patients represent only a few.[13] Given this situation, our aim was to provide weight management support after kidney transplantation while the intervention must have high practicability and patient acceptability. Contextual prerequisites were that the bundle of interventions must contribute to the continuity of care and not lead to further fragmentation of care, while integrating a holistic care approach that balances each patient's medical and behavioral issues with his or her psychosocial needs and concerns. To ensure the relevance of the program for this patient group, kidney recipients were asked both to help define the program's topics and to review the educational material.

Objective

This study's objective was to assess the efficacy of a newly developed behavioral 8-month intervention (versus 1 educational session within the first mo) postrenal transplantation, based on 2 outcomes. The primary outcome was BMI change, as measured in patients with baseline BMIs of ≥18.5 (normal weight or above). Our secondary outcomes were BMI change in patients with BMIs of <18.5 (underweight), and change in physical activity across the entire sample.

MATERIALS AND METHODS

Design

A single-center randomized controlled study was undertaken in the University Hospital Zurich's Division of Nephrology. Data collection started in May 2012 and finished in February 2018. A total of 123 patients were included. Ethical approval was granted by the Ethics Committee of Canton of Zurich, Switzerland (KEK ZH-Nr. 2011-0411).

Eligibility Criteria

Inclusion criteria were adult age (≥18) and having received a kidney or kidney-pancreas transplantation in the past 6 weeks. Exclusion criteria were (1) inability to speak or read German or Italian; or (2) previous or combined lung, liver or heart transplantation.

Data Collection

Patients who fulfilled the eligibility criteria were approached by Advanced Practice Nurse (APN) and informed about the study. If they provided written informed consent, baseline data were collected (first measurement). Then, patients were randomly allocated 1:1 to the usual care (CG) or intervention group (IG). For this purpose, randomization envelopes prepared and sealed by the Cantonal Pharmacy of Zurich using a block randomization of 10 were opened by the APN in front of the patient.

The second measurement took place at month 8 or 9 after completion of the intervention, with a third measurement at month 12 (Figure 1). The intervention was not blinded to the patient; however, the Nephrology team was not informed about group affiliations.

Patients who were approached but declined to participate were asked for written informed consent to allow retrieval of their data from their electronic patient charts.

Usual Care and Intervention

Educational Intervention (CG)

The APN, a master-prepared nurse delivered all patients the same 45- to 60-minute educational intervention. Its content was based on a previously developed brochure[16,17] and tailored to each patient's individual situation, which was explored via a standardized assessment (Intervention 1). Apart from medication self-management, emotional and psychosocial concerns were addressed. The 76-page-long brochure covers topics perceived as relevant by healthcare professionals and/or patients and is based on 3 evidence-based guidelines: the European Best Practice Guidelines, the Kidney Disease Improving Global Outcome, and United Kingdom National Institute of Health and Care Excellence projects. The quality of the guidelines had been evaluated by the first author according to the AGREE criteria and found to be good or excellent.[18] The relevance of weight management, physical activity, and recommendations regarding diet and activity are addressed in detail in the brochure. The content of the brochure was extensively reviewed by clinical experts for correctness and by patients for relevance to the topics for their daily life. As standard postrenal transplantation care, patients were instructed and trained to self-monitor and record their body weight, blood pressure, and pulse daily in a Leporello booklet.

Behavioral Intervention (IG)

In addition to usual care, the IG received additional interventions (interventions 2–8 or 9) focusing on their behavior regarding maintenance/achievement of a normal body weight and the integration of physical activity into a daily routine. Patients included 2–4 weeks posttransplant received a total of 9 interventions, while those included 4–6 weeks posttransplant received 8. Interventions 2 and 3 lasted 45–60 minutes and generally took place at the

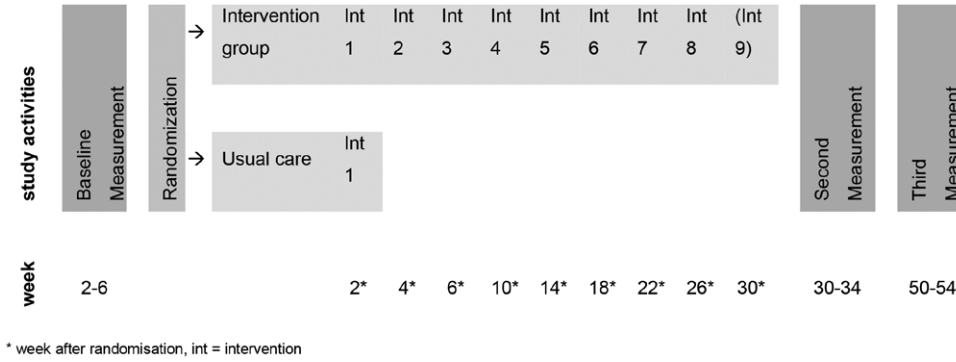

FIGURE 1. Timeline of measurements, randomization, and interventions.

hospital. Interventions 4–9 lasted 15–30 minutes and were conducted by telephone or face to face at the hospital—according to patients' preferences. Counseling followed motivational interviewing technique guidelines.[19,20] Further intervention details are described in Table S1 (**SDC**, http://links.lww.com/TXD/A227) and Figure S1 (**SDC**, http://links.lww.com/TXD/A227).

Outcomes

Primary endpoint:

- Difference in BMI between baseline and month 8 (only in patients with BMIs≥18.5)

Secondary endpoints:
Differences in

- BMI between baseline and month 8 (in patients with BMIs <18.5)
- BMI between baseline and month 12 (in patients with BMIs ≥18.5 and <18.5)
- lean tissue mass (LTM) between baseline and month 8 and 12, and between groups at months 8 and 12
- waist-hip ratio between baseline and month 8 and 12, and between groups at months 8 and 12
- self-reported physical activity at months 8 and 12 (between groups)
- number of steps (total and medium to high activity, via "StepWatch 3" accelerometer) at months 8 and 12 (between groups)

Variables

Body Weight/Height Ratio (kg/m²)

Body mass and height were measured via a SECA suggestion: SECA measuring station and BMI calculated. If necessary, weight was measured in another hospital or at home. With the consent from nonparticipants (NPs), data were extracted from their electronic patient charts. BMI categories matched those of the WHO.[21]

Body Composition

LTM (% of body weight) and lean tissue index (LTI) (LTM in kg/[height in m]²) were assessed with body impedance analysis (Fresenius suggestion: Fresenius). Waist-to-hip ratio was calculated as circumference of the waist divided by the circumference of the hip.

Physical Activity

The self-report instrument asked for the amount of physical activity (intensive, moderate, walking) over the last 7 days.[22] For this study, each patient's overall IPAQ score was calculated in MET (metabolic equivalent of task) minutes per week. The total score was reported to moderately correlate with accelerometer data in previous research (r = 0.30), which is comparable to other self-report instruments assessing physical activity.[23,24] Physical activity was further assessed in months 8 and 12 via the StepWatch 3 suggestion: Stepwatch 3 accelerometer, which differentiates between 3 activity levels: low (1–30 steps/min), medium (31–80 steps/min), and high (≥80 steps/min). Patients were instructed to wear the accelerometer on their ankle for 7 days. Cardiovascular minutes were calculated as the sum of minutes per 7 days that the patient's average step rate was ≥100 per minute for ≥10 minutes.[25]

Perception of Care

The 26-item Patient Assessment of Chronic Illness Care (PACIC) questionnaire assesses chronic care activities based on the Chronic Care Model.[26] It allows 2 scoring options. The first measures patient activation, delivery system, goal setting, problem solving, and follow-up care options and their quality[27]; the second measures how often and how well respondents felt care staff advised, reached agreement with, assisted and arranged resources for them.[28] The instrument showed good internal consistency (Cronbach's alpha ≥0.78) for all subscales and satisfactory convergent validity with the European Project on Patient Evaluation of General Practice Care.[29] Possible scores range from 1 (lowest quality) to 5 (highest quality).

Patient satisfaction with counseling was measured via 11 items rated on a 4-point Likert scale—(1) applies fully, (2) applies mostly, (3) applies partly, and (4) does not apply at all. An exploratory principal component analysis using Varimax Rotation identified 4 dimensions. Of the 11 items, 9 loaded on single components: 2 on "tailored to my situation," 3 on "fostering behavior change," 2 on "quality of material," and 2 on "intended use in future." The remaining 2 were excluded because they loaded on multiple factors, revealing a lack of conceptual clarity. Therefore, the final questionnaire contained 9 items. It was assessed once for each group, at month 1 for the CG and at month 8 for the IG.

Analysis

Sample Size

Analysis of data from a 20-patient pilot study indicated that 2 samples of 64 patients each would achieve 80% power to detect a 1.0 kg/m² difference between the null hypothesis (that both groups' mean change would be 0.0 kg/m²) and the alternative hypothesis (that the mean intervention effect would be ≥1.0 kg/m²), with estimated group standard deviations of 2.0

and 2.0, and with a significance level (alpha) of 0.05 using a 2-sided 2-sample *t*-test. In the sample size calculation for the primary endpoint, patients with BMI < 18.5 (n = 2) and outliers (n = 1) were excluded, resulting in a sample size of 17 for the sample size calculation.

Quantitative Data

The primary endpoint, that is, BMI difference between baseline and month 8, was analyzed with a Mann-Whitney *U* test. A sensitivity analysis was also performed. Log-transformed month 8 IG and CG BMIs were compared via a linear model, while controlling for baseline BMI, depression, and prednisone dose. Secondary endpoints were analyzed via a Mann-Whitney *U* test (for continuous variables) and either a chi-square test or a Fisher exact test (for categorical variables) as appropriate. Treatment groups were tested using a 2-sided significance level of 0.05.

RESULTS

Study Participants

Of the 212 patients who were invited to participate, 123 (58%) were enrolled. Via randomization, 61 were assigned to the IG and 62 to the CG (Figure 2). Of the 89 who declined participation, 87 provided written informed consent for data retrieval from their electronic charts.

Demographic and baseline variables for the overall group (stratified by treatment group) are shown in Table 1. The IG and the CG differed in regard to creatinine (P = 0.011) and eGFR (P = 0.018); all other characteristics were equally distributed.

Treatment Compliance

In the IG, 88.5% of patients participated in ≥7 counseling interviews. While most (86.9%) had ≥4 counseling interviews at the hospital, over half (57.4%) also had ≥3 by telephone. The mean interview duration was 35 minutes for the IG and 64 minutes for the CG. In the CG, 57 (91.9%) patients had 1 counseling session, 5 (8.1%) requested a second one to ensure safe self-management.

Perception of Care

PACIC: Chronic Care Model-Related Activities

Based on data from 10 PACIC questionnaire subscales and 2 summaries, a Mann-Whitney *U* test was used to compare

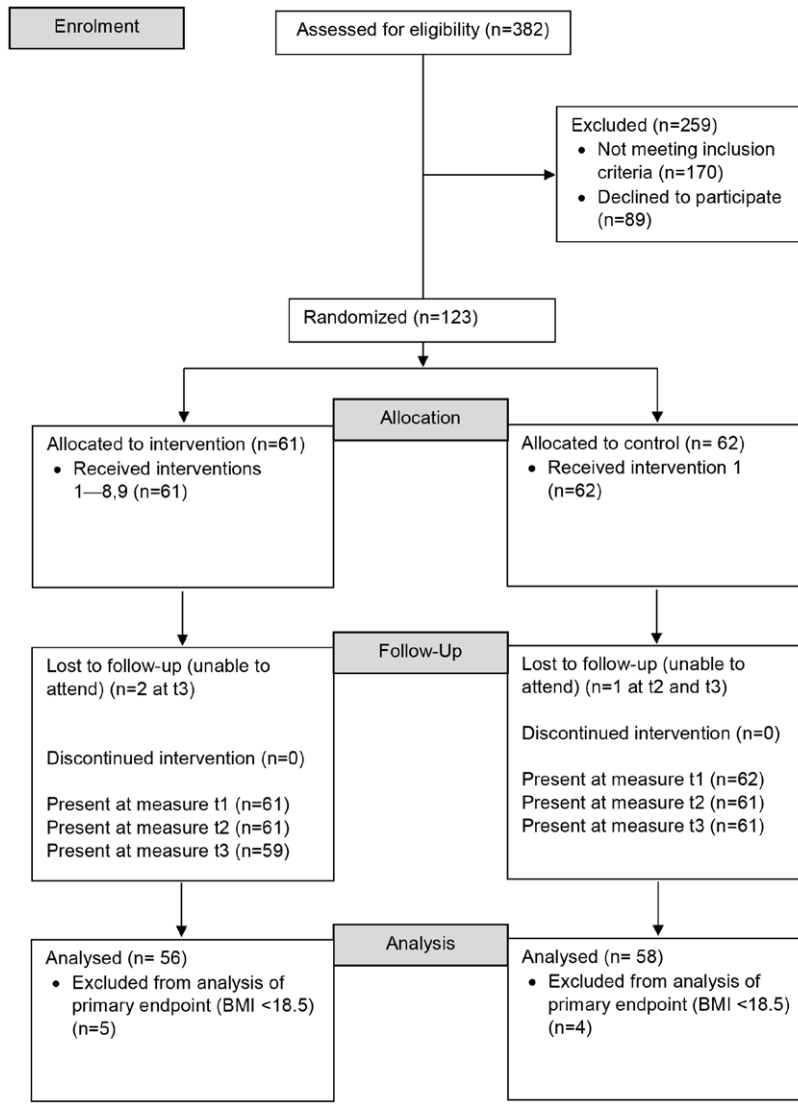

FIGURE 2. Study flow chart.

IG and CG patients' perceptions of the care they had received (Table 2). The differences were statistically significant for all scores except "patient activation."

Satisfaction With Counseling

A Mann-Whitney *U* test was used to compare the data from the 2 groups, regarding Satisfaction with Counseling Questionnaire subscales and 1 summary score (Table 3). No statistically significant differences were found.

Changes in BMI at Months 8 and 12

Month 8

In patients with BMIs ≥18.5, the mean change from baseline BMI to month 8 was 0.039 (95% CI, −0.440 to 0.519) for the IG and 0.143 (95% CI, −0.369 to 0.656) for the CG (Table 4 and Figure 3). A Mann-Whitney *U* test indicated that this difference was nonsignificant ($P = 0.590$). Five patients in the IG and 4 in the CG had baseline BMIs <18.5 (underweight). The mean BMI change from baseline to month 8 in those patients was 1.588 (95% CI, −1.002 to 4.177) for the IG and 2.015 (95% CI, −0.474 to 4.505) for the CG. The exact Mann-Whitney *U* test indicated that this difference was nonsignificant ($P = 0.730$).

Month 12

A Mann-Whitney *U* test was used to compare baseline to month 12 changes between the treatment groups. No statistically significant differences were found for patients with BMIs ≥ 18.5 ($P = 0.454$) and BMIs < 18.5 ($P = 0.730$).

As illustrated in Figure 3, while the IG's overall weight gain was lower than for the CG, stratification reveals varying patterns of weight loss and gain in both groups (nonsignificant). In patients with obesity (BMI ≥ 30), only IG members (n = 7, versus 11 in the CG) showed ongoing weight loss after both 8 and 12 months.

Body Composition

Changes in both treatment groups' LTI from baseline to month 8 and month 12 were compared via a Mann-Whitney *U* test. No statistically significant differences were detected at month 8 (all $P = 0.985$, female $P = 0.409$, male $P = 0.564$) or month 12 (all $P = 0.413$, female $P = 0.289$, male $P = 0.795$); nor were any significant differences detected between the groups at month 8 (all $P = 0.472$, female $P = 0.481$, male $P = 0.124$) or 12 (female and male $P = 0.616$, female $P = 0.371$, P = male 0.279) (Figure 4). Waist-to-hip ratio decreased slightly in both groups over the entire 12 months (Figure 5); however, no significant difference between the groups was detected.

Physical Activity at Month 8 and 12

Accelerometer

The average daily numbers of steps and of steps with medium to high activity cadence of the 2 treatment groups at months 8 and 12 were compared via a Mann-Whitney *U* test. Both groups walked between 9773 and 11 217 steps per day, of which between 6870 and 8260 were of moderate or high intensity (Figure 6). No statistically significant differences

TABLE 1.

Demographic and clinical characteristics of all randomized patients (N = 123) at baseline and patients who declined participation (N = 87)

	Overall	IG	CG	NP
N	**123**	**61**	**62**	**87**
Age, mean (SD)	50.2 (13.1)	50.5 (13.8)	49.8 (12.6)	51.0 (15.4)
Kidney transplantation (%)	120 (97.6)	60 (98.4)	60 (96.8)	82 (94.3)
Kidney-pancreas transplantation (%)	3 (2.4)	1 (1.6)	2 (3.2)	5 (5.7)
First transplantation (%)	98 (79.7)	53 (86.9)	45 (72.6)	69 (79.3)
Gender = male (%)	76 (61.8)	37 (60.7)	39 (62.9)	56 (64.4)
Creatinine at baseline, mean (SD)	141.8 (50.5)	132.9 (46.2)	150.6 (53.3)	144.8 (52.9)
eGFR at baseline, mean (SD)	49.9 (15.9)	52.8 (15.4)	47.0 (15.9)	48.8 (18.0)
Urea at baseline, mean (SD)	10.2 (4.2)	10.0 (5.0)	10.3 (3.4)	10.7 (4.1)
Hemoglobin at baseline, mean (SD)	107.7 (17.1)	109.6 (17.0)	105.8 (17.0)	103.9 (15.9)
Hypertension = yes (%)	54 (43.9)	28 (45.9)	26 (41.9)	44 (51.2)
Diabetes at time of transplantation (%)	14 (11.4)	6 (9.8)	8 (12.9)	17 (19.5)
Smoking at baseline = yes (%)	14 (11.4)	10 (16.4)	4 (6.5)	Not assessed
Prednison, mg/day				
Baseline, mean (SD)	20.1 (8.9)	20.6 (8.3)	19.6 (9.5)	20.4 (8.6)
Mo 8, mean (SD)	5.3 (13.5)	6.4 (18.8)	4.3 (3.9)	4.6 (3.1)
Mo 12, mean (SD)	3.0 (3.7)	2.9 (3.5)	3.2 (3.9)	3.5 (3.6)
Etiology (%)				
Diabetes Type 1 or 2	7 (5.7)	3 (4.9)	4 (6.5)	10 (11.4)
Hypertensive kidney disease	9 (7.3)	3 (4.9)	6 (9.7)	4 (4.6)
Glomerulonephritis	43 (35.0)	18 (29.5)	25 (40.3)	34 (39.1)
Polycystic kidney disease	28 (22.8)	20 (32.8)	8 (12.9)	14 (16.1)
Congenital genetic kidney disease	12 (9.8)	7 (11.5)	5 (8.1)	6 (6.9)
Genetic (others than polycystic)	7 (5.7)	2 (3.3)	5 (8.1)	1 (1.1)
Unknown	15 (12.2)	7 (11.5)	8 (12.9)	11 (12.6)
Others	2 (1.6)	1 (1.6)	1 (1.6)	7 (8.0)

CG, control group; IG, intervention group; NP, nonparticipant; SD, standard deviation.

TABLE 2.

PACIC at month 8, stratified by treatment group

	Description of the score [27, 28]	IG	CG	*P*
N		61	62	NA
PACIC sum, mean (SD)		3.8 (0.6)	3.2 (0.8)	0.000
PACIC activation, mean (SD)	Actions that solicit patient input and involvement in decision-making	4.0 (0.8)	3.7 (1.1)	0.577
PACIC delivery, mean (SD)	Actions that organize care and provide information to patients to enhance their understanding of care	4.5 (0.6)	4.1 (0.8)	0.007
PACIC goal, mean (SD)	Acquiring information for and setting of specific, collaborative goals	3.6 (0.8)	2.7 (1.0)	0.000
PACIC problem, mean (SD)	Considering potential barriers and the patient's social and cultural environment in making treatment plans	4.0 (0.8)	3.3 (1.2)	0.002
PACIC follow-up, mean (SD)	Arranging care that extends and reinforces office-based treatment, and making proactive contact with patients to assess progress and coordinate care	3.1 (1.0)	2.6 (1.1)	0.032
AS sum, mean (SD)		3.9 (0.6)	3.3 (0.9)	0.000
AS assessment, mean (SD)	Ask about/assess behavioral health risk(s) and factors affecting choice of behavior change goals/methods	4.0 (0.8)	3.5 (0.9)	0.010
AS advice, mean (SD)	Give clear, specific, and personalized behavior change advice, including information about personal health harms and benefits	3.7 (0.7)	3.1 (0.9)	0.000
AS agreement, mean (SD)	Collaboratively select appropriate treatment goals and methods based on the patient's interest in and willingness to change the behavior	4.1 (0.8)	3.2 (1.0)	0.000
AS assistance, mean (SD)	Using behavior change techniques (self-help and/or counseling), aid the patient in achieving agreed-upon goals by acquiring the skills, confidence, and social/environmental supports for behavior change, supplemented with adjunctive medical treatments when appropriate	3.5 (0.8)	2.8 (1.1)	0.002
AS arrangement, mean (SD)	Schedule follow-up contacts (in person or by telephone) to provide ongoing assistance/support and to adjust the treatment plan as needed, including referral to more intensive or specialized treatment	3.1 (1.0)	2.6 (1.1)	0.025

CG, control group; IG, intervention group; PACIC, Patient Assessment of Chronic Illness Care; SD, standard deviation.

TABLE 3.

Satisfaction with counseling at month 1 for CG and at month 8 for IG, stratified by treatment group

	IG	CG	*P*
Tailored to my situation (N)	53	51	
Tailored to my situation, mean (SD)	1.30 (0.44)	1.48 (0.51)	0.088
Fostering behavior change (N)	54	38	
Fostering behavior change, mean (SD)	1.48 (0.49)	1.65 (0.53)	0.089
Quality of material (N)	54	49	
Quality of material, mean (SD)	1.30 (0.46)	1.18 (0.43)	0.095
Intended use in future (N)	53	48	
Intended use in future, mean (SD)	1.23 (0.49)	1.23 (0.41)	0.601
Sum score (N)	50	30	
Sum score, mean (SD)	1.33	1.37	0.261

CG, control group; IG, intervention group; SD, standard deviation.

TABLE 4.

BMI at baseline, month 8 and 12, stratified by BMI ≥18.5 and <18.5 kg/m² at baseline, of participants and patients who declined participation (NP)

	Baseline			Mo 8			Mo 12		
	IG	CG	NP	IG	CG	NP	IG	CG	NP
BMI <18.5 (N)	5	4	2	5	4	2	5	4	2
BMI <18.5, mean (SD)	17.77 (0.43)	17.69 (0.48)	17.63 (0.27)	19.36 (1.88)	19.71 (2.03)	17.83 (0.21)	19.60 (1.66)	19.97 (2.66)	18.59 (1.10)
BMI ≥18.5 (N)	56	58	84	56	58	79	56	58	79
BMI ≥18.5, mean (SD)	25.06 (3.61)	26.01 (4.66)	25.38 (4.03)	25.10 (3.39)	26.15 (4.37)	25.77 (4.11)	25.09 (3.49)	26.20 (4.37)	25.68 (4.09)
Further stratified									
18.5 ≤ BMI <25 (N)	27	25	39	27	25	38	27	25	37
18.5 ≤ BMI <25, mean (SD)	22.09 (1.71)	21.76 (1.94)	21.78 (1.76)	22.77 (1.82)	22.60 (2.29)	22.84 (2.82)	22.73 (2.23)	22.71 (2.48)	22.87 (2.58)
25 ≤ BMI <30 (N)	22	22	36	22	22	34	22	22	34
25 ≤ BMI <30, mean (SD)	26.58 (1.10)	27.19 (1.59)	27.48 (1.49)	26.08 (2.10)	27.14 (2.08)	27.66 (2.40)	26.18 (2.05)	27.01 (1.96)	27.13 (2.83)
BMI ≥30 (N)	7	11	9	7	11	7	7	11	8
BMI ≥30, mean (SD)	31.75 (1.45)	33.29 (1.74)	32.58 (1.74)	31.00 (2.67)	32.24 (3.53)	32.52 (3.33)	30.75 (2.89)	32.49 (3.27)	32.52 (3.08)

CG, control group; IG, intervention group; NP, nonparticipant; SD, standard deviation.

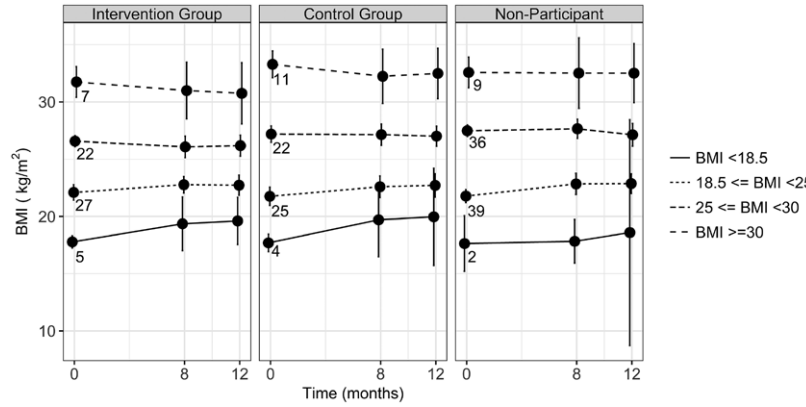

FIGURE 3. BMI at baseline, month 8 and 12, stratified by treatment group and baseline BMI. Error bars show mean and 95% confidence interval. Number of patients.

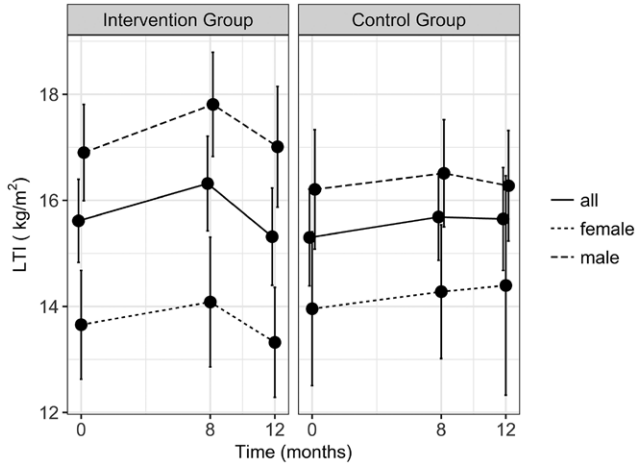

FIGURE 4. LTI at baseline, month 8 and 12, stratified by treatment group and gender. Error bars show mean and 95% confidence interval. LTI, lean tissue index.

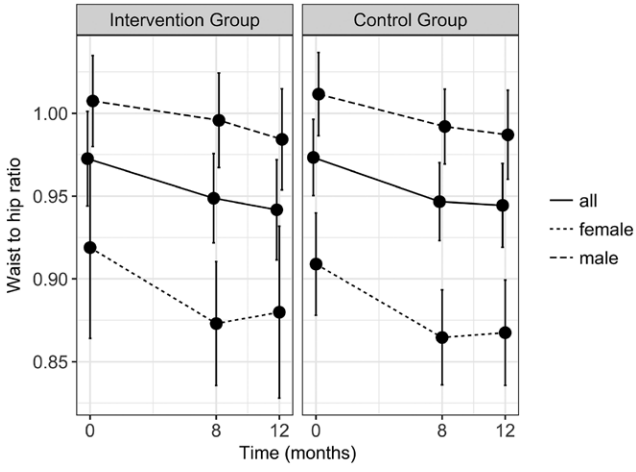

FIGURE 5. Waist-to-hip ratio at baseline, month 8 and 12, stratified by treatment group and gender. Error bars show mean and 95% confidence interval.

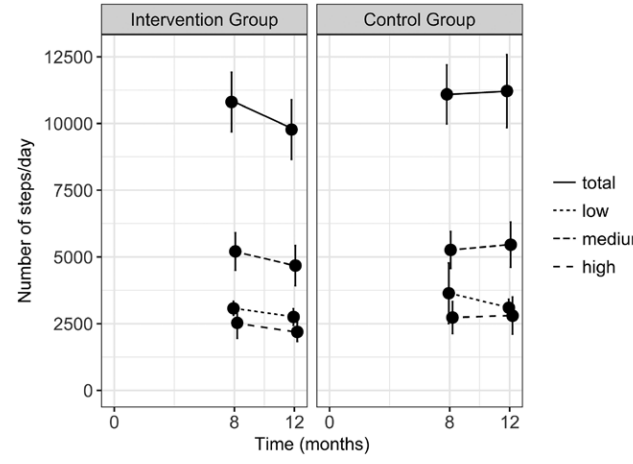

FIGURE 6. Number of steps at month 8 and 12, stratified by intensity. Error bars show mean and 95% confidence interval.

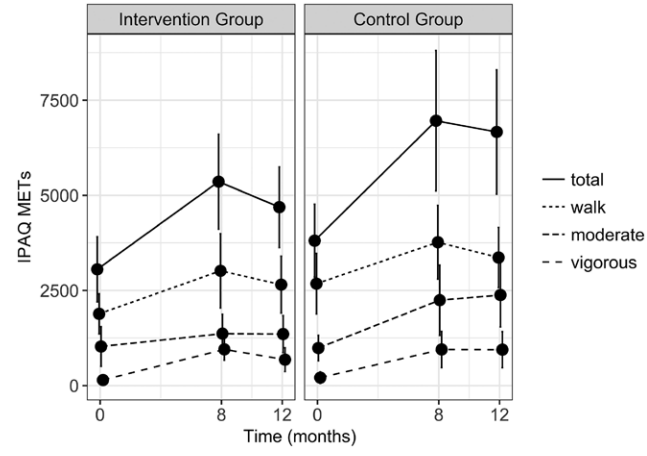

FIGURE 7. IPAQ METs at baseline, month 8 and 12, stratified by intensity. Error bars show mean and 95% confidence interval. MET, metabolic equivalent of task.

were found either for average daily number of steps (mo 8 $P = 0.823$; mo 12 $P = 0.195$) or for average daily number of steps with medium to high activity cadence (mo 8 $P = 0.748$; mo 12 $P = 0.163$). Similarly, numbers of cardiovascular minutes did not differ significantly (mo 8 $P = 0.586$; mo 12 $P = 0.851$).

IPAQ Scores

A Mann-Whitney *U* test comparing intervention and CG IPAQ scores for walking, moderate, vigorous, and sum of

moderate and vigorous exercise at months 8 and 12 indicated no significant differences (walking [mo 8 P = 0.156, mo 12 P = 0.211], moderate [mo 8 P = 0.191, mo 12 P = 0.223], vigorous [mo 8 P = 0.141, mo 12 P = 0.603], sum of moderate and vigorous [mo 8 P = 0.797, mo 12 P = 0.363] or the sum score [mo 8 P = 0.760, mo 12 P = 0.248]) (Figure 7).

DISCUSSION

This RCT's aim was to evaluate the effect of an 8-month behavioral intervention on weight and physical activity to provide guidance for evidence-based posttransplant care. As intended, while both groups were highly satisfied with the intervention module they shared, the IG received considerably more chronic-care related training from their nephrology team than the CG.

Both IG and CG patients showed good weight management over the full 12 month measurement period: those with BMIs <18.5 were able to increase their body weight to the normal range in both groups; those with BMIs ≥18.5 were able to maintain their mean BMI in the IG (+0.03 kg/m^2); the CG had only a minimal mean BMI increase (+0.19 kg/m^2).

Although the intervention appeared to produce a significant change (−1.0 kg/m^2) in our pilot study, the full study's 8-month intervention effect was not superior to that of the single educational session, that is, sample size was too small to detect any change with a power of 80%. We can suggest 3 explanations for the difference in treatment effect between the pilot and in the full study: Firstly, post hoc analysis revealed an uneven distribution of normal weight patients between the pilot's IG (5 of 9 patients, 56%) and CG (3 of 8 patients, 38%). In contrast, the full study's distribution was even across the 2 groups. As initial BMI may be a risk for weight gain,[30,31] for example, due to long-term dietary habits, the pilot CG's higher percentage of patients with overweight or obesity, and possibly a higher risk for weight gain may have increased the difference between it and the IG. Secondly, fidelity to the intervention was not fully provided: 8.1 % of the CG received a second intervention, mainly to ensure safe self-management, and 12.5% of the IG had <7 intervention sessions, mainly due to re-hospitalizations. The provision of more care to the CG and omission of interventions in the IG may have masked noteworthy CG-IG differences. Thirdly, statistical outliers were excluded in the pilot due to its small sample size, but were included in the final study. This difference in statistical methodology may have contributed to an overestimation of the pilot study's treatment effect.

In sum, both the IG and the CG demonstrated good weight management. Several factors might explain why weight gain was a less serious issue than initially expected.

Firstly, our study cohorts' success in weight management may reflect their high mean physical activity level. Both groups were walking over 10 000 steps per day at month 8, with around two-thirds of those steps performed at medium to high intensity. Still, cardiovascular minutes were lower than the recommended 150 per week. These were probably underreported because we counted only step-based activity and steps with high cadence. Thus, walking uphill may be at lower cadence, but still be intense for patients.

Second, our results may reflect a Hawthorne effect, that is, the tendency of test subjects to behave differently when under observation, or a selection bias, including more patients who were motivated toward weight control. In this study, NPs with BMIs ≥18.5 who received the control intervention had a mean increase in BMI from baseline to month 12 of 0.34 kg/m^2, which is slightly higher than observed in either the CG or the IG.

Third, our selection criteria may have resulted in a sample less prone to weight gain than the overall Swiss cohort. Reselecting according to that cohort's sample criteria and including only first kidney recipients, the mean BMI of our 95 (of 123) participants and our 65 (of 87) NPs was 25.29 at baseline and 25.66 at month 12, resulting in a mean BMI change of +0.37 kg/m^2 over the year. The Swiss cohort's mean Baseline BMI was 25.8 and 26.4 at month 12, resulting in an average weight gain of +0.6 kg/m^2.[2] Unlike the Swiss cohort, we excluded non-German- or Italian-speaking patients, suggesting that patients with immigration backgrounds are particularly prone to first year posttransplant weight gain. Further research is needed in this regard.

LTI increased slightly from baseline to month 8 and decreased slightly between months 8 and 12. The values of this population are within the reference values—approximately 12–16 LTI (kg /m^2) for woman and approximately 15–20 LTI (kg /m^2) for men 50 years of age[32] here. According to the WHO, the risk of metabolic complications is increased by a waist-hip ratio of ≥0.85 for women and ≥0.90 for men.[33] Although our sample's waist-to-hip-ration decreased over the 12 months, the means were higher for both groups at all measurement points. A main factor for the higher ratio may be steroid use, which leads to fat redistribution to the abdomen.

Strengths and Limitations of the Study and Intervention

This complex intervention's main strength is the high level of patient involvement throughout the entire study period. This led to high patient acceptability, which was reflected in low drop-out rates. As a weakness, our sample size calculation was based on a much higher weight gain effect (BMI change of 1 kg/m^2). In the final study, then, the effect was much smaller, leading to a lack of statistical power.

Recommendation for Practice and Future Research

Both interventions (usual care and IG) helped patients with normal weight to maintain weight and patients with overweight and obesity to lose weight in the first year after transplantation. This indicates that BMI category (underweight, normal, overweight, obesity) at time of transplantation may be a useful criterion for stratifying the dose (one versus several) and manner (educational versus behavioral) of intervention. However, other risk factors for weight gain may also be relevant. Further research is needed to explore which patients benefit from more complex interventions.

CONCLUSIONS

This behavioral weight and activity intervention had excellent acceptability and supported patients in controlling weight gain, but showed no statistical significant advantage over a single educational session. To recommend stratified interventions based on patients' risk profiles, further research will need to focus on risk factors for weight gain in all BMI categories.

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REFERENCES

1. Kasiske BL, Zeier MG, Chapman JR, et al; Kidney Disease: Improving Global Outcomes. KDIGO clinical practice guideline for the care of kidney transplant recipients: a summary. *Kidney Int.* 2010;77:299–311.
2. Beckmann S, Nikolic N, Denhaerynck K, et al. Evolution of body weight parameters up to 3 years after solid organ transplantation: the prospective Swiss Transplant Cohort Study. *Clin Transplant*. 2017;31:1–11.
3. Zelle DM, Kok T, Dontje ML, et al. The role of diet and physical activity in post-transplant weight gain after renal transplantation. *Clin Transplant.* 2013;27:E484–E490.
4. Lafranca JA, IJermans JN, Betjes MG, et al. Body mass index and outcome in renal transplant recipients: a systematic review and meta-analysis. *BMC Med.* 2015;13:111.
5. Bundesamt für Gesundheit, Bundesamt für Statistik. *Schweizerische Gesundheitsbefragung 2012: Übergewicht und Adipositas*. Federal Office of Public Health (FOPH). Neuchatel, Switzerland;2014.
6. Ahmadi SF, Zahmatkesh G, Streja E, et al. Body mass index and mortality in kidney transplant recipients: a systematic review and meta-analysis. *Am J Nephrol.* 2014;40:315–324.
7. Sood A, Hakim DN, Hakim NS. Consequences of recipient obesity on postoperative outcomes in a renal transplant: a systematic review and meta-analysis. *Exp Clin Transplant.* 2016;14:121–128.
8. Hill CJ, Courtney AE, Cardwell CR, et al. Recipient obesity and outcomes after kidney transplantation: a systematic review and meta-analysis. *Nephrol Dial Transplant.* 2015;30:1403–1411.
9. Nicoletto BB, Fonseca NK, Manfro RC, et al. Effects of obesity on kidney transplantation outcomes: a systematic review and meta-analysis. *Transplantation.* 2014;98:167–176.
10. Chang SH, McDonald SP. Post-kidney transplant weight change as marker of poor survival outcomes. *Transplantation.* 2008;85:1443–1448.
11. Kim Y, Kim JR, Choi H, et al. Patients with persistent new-onset diabetes after transplantation have greater weight gain after kidney transplantation. *J Korean Med Sci.* 2013;28:1431–1434.
12. Ducloux D, Kazory A, Simula-Faivre D, et al. One-year post-transplant weight gain is a risk factor for graft loss. *Am J Transplant.* 2005;5:2922–2928.
13. Orazio LK, Murray EM, Campbell KL. Guideline use: a survey of dietitians working with adult kidney transplant recipients. *Nephrology (Carlton).* 2012;17:508–513.
14. Guida B, Trio R, Laccetti R, et al. Role of dietary intervention on metabolic abnormalities and nutritional status after renal transplantation. *Nephrol Dial Transplant.* 2007;22:3304–3310.
15. Kidney Disease: Improving Global Outcomes (KDIGO) Transplant Work Group. KDIGO clinical practice guideline for the care of kidney transplant recipients. *Am J Transplant*. 2009;9 Suppl 3:S1–155.
16. Transplantationszentrum Universitätsspital Zürich. Wissenswertes für das Leben nach einer Nierentransplantation: Broschüre 3 (German version). In: *Klinik für Nephrologie Universitätsspital Zürich*. Zürich: Transpantationszentrum Universitätsspital Zürich; 2011:1–76.
17. Centro Trapianti Clinica Universitaria di Zurigo. Informazioni necessarie per la vita dopo und trapianto di rene: Brochure 3 (Italian version). In: *Clinica di nefrologia Clinica Universitaria di Zurigo*. Zurigo: 2011:1–76.
18. Brouwers MC, Kerkvliet K, Spithoff K; AGREE Next Steps Consortium. The AGREE reporting checklist: a tool to improve reporting of clinical practice guidelines. *BMJ.* 2016;352:i1152.
19. Miller WR, Rollnick S. *Motivational Interviewing: Preparing People for Change*. New York, NY: The Guilford Press; 2002.
20. Lundahl B, Moleni T, Burke BL, et al. Motivational interviewing in medical care settings: a systematic review and meta-analysis of randomized controlled trials. *Patient Educ Couns.* 2013;93:157–168.
21. World Health Organization. Obesity: preventing and managing the global epidemic – report of a WHO consultation. *World Health Organisation Technical Report Series* 2008:1–253.
22. IPAQ group. IPAQ: International Physical Activity Questionnaire. Available at https://sites.google.com/site/theipaq/questionnaire_links. Published 2019. Accessed July 31, 2019.
23. Craig CL, Marshall AL, Sjöström M, et al. International physical activity questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc*. 2003;35:1381–1395.
24. Hallal PC, Gomez LF, Parra DC, et al. Lessons learned after 10 years of IPAQ use in Brazil and Colombia. *J Phys Act Health.* 2010;7 Suppl 2:S259–S264.
25. Tudor-Locke C, Han H, Aguiar EJ, et al. How fast is fast enough? Walking cadence (steps/min) as a practical estimate of intensity in adults: a narrative review. *Br J Sports Med.* 2018;52:776–788.
26. Epping-Jordan JE, Pruitt SD, Bengoa R, et al. Improving the quality of health care for chronic conditions. *Qual Saf Health Care*. 2004;13:299-305.
27. Glasgow RE, Wagner EH, Schaefer J, et al. Development and validation of the patient assessment of chronic illness care (PACIC). *Med Care.* 2005;43:436–444.
28. Whitlock EP, Orleans CT, Pender N, et al. Evaluating primary care behavioral counseling interventions: an evidence-based approach. *Am J Prev Med.* 2002;22:267–284.
29. Rosemann T, Laux G, Droesemeyer S, et al. Evaluation of a culturally adapted German version of the Patient Assessment of Chronic Illness Care (PACIC 5A) questionnaire in a sample of osteoarthritis patients. *J Eval Clin Pract*. 2007;13:806–813.
30. Chan W, Bosch JA, Jones D, et al. Obesity in kidney transplantation. *J Ren Nutr.* 2014;24:1–12.
31. Ersoy A, Baran B, Ersoy C, et al. Calcineurin inhibitors and post-transplant weight gain. *Nephrology (Carlton).* 2008;13:433–439.
32. Fresenius Medical Care Germany. Body Composition Monitor: Reference Range. Available at http://www.bcm-fresenius.de/cps/rde/xchg/SID-C735597B-CAAE68AE/fme-bcm/hs.xsl/23.htm. Accessed September 26, 2018.
33. World Health Organization. *Waist circumference and waist-hip ratio: Report of a WHO expert consultation: Geneva, 8-11 December 2008*. Geneva, Switzerland: World Health Organization;2011.