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Preventive Intervention for Living Donor Psychosocial Outcomes: Feasibility and Efficacy in a Randomized Controlled Trial

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There are no evidence-based interventions to prevent adverse psychosocial consequences after living donation. We conducted a single-site randomized controlled trial to examine the postdonation impact of a preventive intervention utilizing motivational interviewing (MI) to target a major risk factor for poor psychosocial outcomes, residual ambivalence (i.e. lingering hesitation and uncertainty) about donating. Of 184 prospective kidney or liver donors, 131 screened positive for ambivalence; 113 were randomized to (a) the MI intervention, (b) an active comparison condition (health education) or (c) standard care only before donation. Ambivalence was reassessed postintervention (before donation). Primary trial outcomes—psychosocial variables in somatic, psychological and family interpersonal relationship domains—were assessed at 6 weeks and 3 months postdonation. MI subjects showed the greatest decline in ambivalence ($p = 0.050$). On somatic outcomes, by 3 months postdonation MI subjects reported fewer physical symptoms ($p = 0.038$), lower rates of fatigue ($p = 0.021$) and pain ($p = 0.016$), shorter recovery times ($p = 0.041$) and fewer unexpected medical problems ($p = 0.023$). Among psychological and interpersonal outcomes, they had a lower rate of anxiety symptoms ($p = 0.046$) and fewer unexpected family-related problems ($p = 0.045$). They did not differ on depression, feelings about donation or family relationship quality. The findings suggest that the intervention merits testing in a larger, multisite trial.

Key words: Ambivalence, kidney donor, liver donor, living donor, psychosocial outcomes

Abbreviations: ANOVA, analysis of variance; GAD-7, Generalized Anxiety Disorder-7; IDA, independent donor advocate; IQR, interquartile range; MI, motivational interviewing; NNT, number needed to treat; PHQ-9, Patient Health Questionnaire-9; PD, prospective donor; RCT, randomized controlled trial.

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Introduction

Living donation is a mainstay of transplantation due to both the continued organ shortage and the medical benefits for transplant recipients (1,2). However, the need for living donors must be balanced against the risks to these individuals, who undergo surgery for no personal medical benefit (2–4). Indeed, among the highest priorities in transplantation are the protection of donors' well-being and the prevention of adverse consequences of donation; these priorities drive the continued refinement of practice guidelines and requirements designed to promote donor safety (5–9).

The mandate to protect donors compels attention to not only medical but psychosocial outcomes. Recent reviews of the donor psychosocial outcomes literature suggest that, although many individuals experience no adverse psychosocial consequences of donation, others develop enduring somatic complaints (e.g. fatigue, pain), psychological distress (e.g. depressive or anxiety symptoms) and/or

strained relationships with family members (10–16). Over half of all donors may experience such difficulties (11).

These findings are striking given rigorous evaluation protocols designed to screen out potential donors with significant medical or psychosocial contraindications to donation (7,8,17–20). These protocols' success is evidenced by descriptive studies' findings that individuals approved as donors show high levels of physical, psychological and social well-being relative to normative or comparison groups (21–28). However, to the extent that even carefully selected donors are at risk for adverse psychosocial outcomes postdonation, additional strategies are required to ensure that donors' well-being is preserved.

There are no evidence-based interventions available to prevent poor postdonation psychosocial outcomes. We sought to address this gap by developing a ''selective'' preventive intervention, that is, one focused on a key risk factor for postdonation psychosocial difficulties (29,30). Namely, residual ambivalence about donating—i.e. lingering feelings of hesitation and uncertainty that remain after the prospective donor's (PD's) predonation evaluation and that coexist with his/her intention to donate—is not only prevalent but one of the few factors consistently found to predict poor postdonation psychosocial outcomes (10,11,31–37). Residual ambivalence is distinct from acute ambivalence, or feelings of indecision so marked that the PD is deemed unable to donate (6,38,39). Although acute ambivalence, resulting in the individual being ruled out as a donor, is rare ($\leq$3% of rule-outs) (17,40,41), some degree of residual ambivalence shortly before donation has been noted in up to 75% of donors (11,27,31,33,34).

We reasoned that if an intervention targeted predonation residual ambivalence, poor postdonation psychosocial outcomes—the primary outcomes in the current study—might be prevented. To this end, our intervention utilizes a novel application of motivational interviewing (MI) (42,43). The intervention puts MI to a use for which it is well-suited but has been overlooked. In all past MI clinical and research applications, the aim has been to enhance motivation for behavior change (44–46). However, equally important is MI's focus on exploring and resolving ambivalence, no matter what the individual's ultimate choice regarding any behavior they might undertake, or decision they might make (42). The goal of our MI intervention is neither to encourage nor to discourage donation, but to enable PDs to resolve residual ambivalence associated with their own decisions about donation, and hence to prevent psychosocial difficulties in these individuals after donation.

Building on developmental work showing that the MI intervention was acceptable and relevant to PDs' concerns (11), we now present results from a Phase II (47) randomized controlled trial (RCT) designed to examine intervention feasibility and efficacy. We hypothesized that the MI intervention would not only reduce predonation residual ambivalence, relative to that in individuals not receiving the intervention, but lead to lower rates of postdonation difficulties in our primary trial outcomes: psychosocial variables in somatic, psychological and family relationship domains.

Table 1: Subject inclusion criteria

Criterion
Aged $\geq$18
Approved as a living kidney or liver donor and scheduled for surgery at the University of Pittsburgh Medical Center
Able to speak English
Access to a telephone
Willing to provide informed consent
Score $>$ 0 on Simmons Ambivalence Scale[1]

[1]This scale had an internal consistency reliability $\alpha = 0.81$ in our cohort.

Methods

Subjects

Table 1 lists subject inclusion criteria. The key criterion was that PDs show at least some residual ambivalence, based on screening with the Simmons Ambivalence Scale (32). This scale has established psychometric properties (31,34,35,37). A recent editorial supports its choice for assessing donor ambivalence (48). It includes seven items (e.g. ''I would really want to donate, even if someone else could do it''). The number of items on which ambivalent feelings are present is tallied (range, 0–7); a total score $>$ 0 identifies ambivalence (31,34,35). We adopted this low threshold (consistent with past studies) because ambivalence underreporting is possible: individuals close to the point of donation may perceive it as inconsistent to express strong reservations about donating (34).

Trial design

Using a parallel groups design, subjects were randomized 2:2:1 to (a) the MI intervention (plus standard care), (b) an active comparison condition to control for the effects of contact time and attention (plus standard care) or (c) standard care only (our center's educational information provided to all PDs). The rationale for unequal randomization lay in our feasibility goals of examining whether subjects would agree to and complete all procedures in the active arms (49). The computer-generated randomization schedule was prepared by a study team member not responsible for subject enrollment or assignment to conditions. The random allocation sequence was concealed from other team members. The schedule used permuted blocks of randomly varying size to limit predictability and imbalances in intervention assignment over the study.

Procedures

The University of Pittsburgh Institutional Review Board approved the study. Interventions and assessments were by telephone. During 24 months of recruitment (ending August 2012), the study coordinator administered the Ambivalence Scale to potential subjects at baseline (T0). If eligible, the coordinator enrolled and informed them of their study condition assignment. The MI intervention and active comparison condition were delivered by trained health professionals (nurses, social workers) before any donation surgery. Separate interventionists conducted the MI versus active comparison condition in order to eliminate cross-condition contamination.

Figure 1 shows the timeline of interventions and assessments relative to donation-related events. Outcomes assessors at T1, T2 and T3 were blinded as to which condition subjects were assigned.

Interventions

MI intervention: We previously described the intervention's conceptual underpinnings and development (11). It involved two 30- to 45-min telephone sessions with each PD during an approximately 1-week time period. We used standard MI techniques (42,44) (e.g. reflective listening) and sessions focused on (a) encouraging PDs to explain how they came to consider donation, (b) helping PDs ''hear'' their motivations for/against donation, (c) reviewing PDs' item-by-item results on the Ambivalence Scale (administered at screening) and (d) completing MI exercises (e.g. Values Card Sort (42)) to assist PDs to recognize their most important goals and values, and how proceeding with living donation (or deciding not to do so) is linked to those goals/values. Plans were developed for any actions PDs could take between sessions to resolve residual ambivalence (e.g. obtaining more information). Results of these efforts were reviewed during the second session.

Active comparison condition: enhanced standard care: This condition's two 30- to 45-min telephone sessions consisted of didactically presented educational information on healthy lifestyle issues (e.g. eating habits, exercise). Our rationale for this was threefold. First, because PDs received some such information during their medical/psychosocial evaluation, our presentation did not introduce completely new information. Thus, a basic equivalence across study subjects could be maintained. Second, healthy lifestyle information is pertinent but not specific to living donors; its brief consideration was unlikely to have a major impact on ambivalence or postdonation outcomes. Third, by presenting material didactically, we sought to avoid opportunities for PDs to engage in personal reflection about donation that could affect our outcomes.

Quality control and intervention fidelity: MI and Enhanced Standard Care interventionists received training and supervision by an expert MI trainer (A.Z.) or health educator (A.D.D.). During training and supervision, one-on-one feedback was provided using evaluations of intervention session audiotapes. In addition, MI sessions were rated according to MI competency benchmarks (50). For this, cases were randomly selected and one 20-min segment per case was rated by raters trained on the MI Treatment Integrity system (50). Interventionist competency ratings exceeded thresholds required (scores $\geq$4 on a 5-point scale for each competency area), and interventionist behavior counts (e.g. use of reflective statements) exceeded competency requirements (50). We developed an instrument to assess fidelity to the Enhanced Standard Care sessions; we required and found that $\geq$95% of elements of these informational sessions were presented according to sessions' scripted wording.

Assessments and primary outcome measures

In addition to examining feasibility (e.g. rates of intervention completion) and sample descriptive characteristics, we reassessed at T1 (postintervention) whether each PD continued to intend to donate, and we readministered the Ambivalence Scale.

Among subjects completing donation surgery, we assessed variables in three primary outcome domains (Table 2). Except where noted, outcomes were assessed at both 6 weeks and 3 months postdonation.

Postdonation perceived physical health and somatic complaints: Five measures were used (Table 2). Because distributions of fatigue and pain scores were skewed, we determined whether subjects reported any (vs. no) current fatigue and any current pain and used these dichotomous variables in all analyses.

Postdonation psychological distress: Three measures were administered (Table 2). With respect to symptoms, we focused on depression and anxiety because such symptoms are more prevalent than any others in living donors (11). Because the psychological measures' distributions were skewed, we applied clinical thresholds (64) to identify the presence of any depression (PHQ-9 $\geq$5) or any anxiety (GAD-7 $\geq$5), and we determined whether any (vs. no) negative feelings about donation were reported (score $>$0).

Postdonation familial relationship strain: Three measures were administered (Table 2).

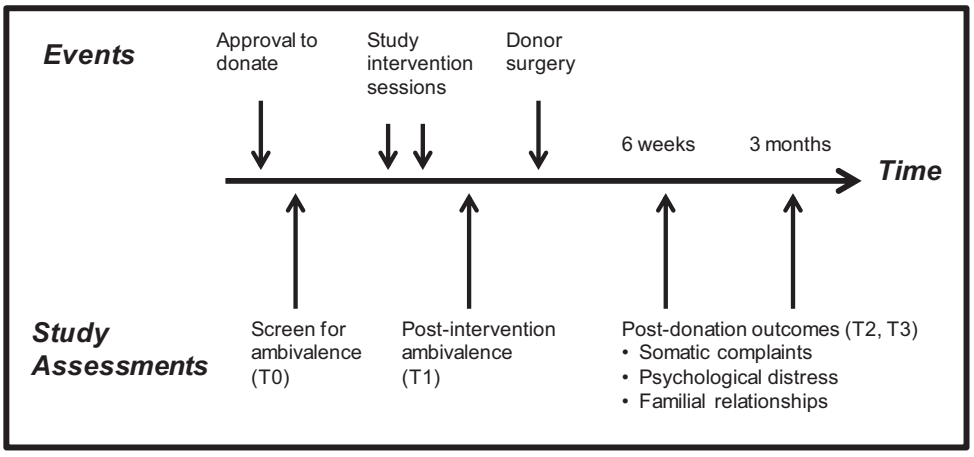

Figure 1: Study procedures timeline. The postdonation assessment timepoints in this initial efficacy study were selected for several reasons. The 6-week point was selected in order to begin to track donor outcomes after they had recovered from the immediate effects of surgery. Donors were followed up through 3 months because other studies document negative psychosocial outcomes within this time frame (10,11).

Table 2: Instruments used to assess postdonation outcomes

Outcome variable	Postdonation timepoints at which outcome was assessed	Instrument and description	No. of items	Cronbach's α, current sample	Source[1]
Postdonation physical health and somatic complaints domain					
No. of physical symptoms related to donation	6 weeks, 3 months	Checklist of Donation-Related Physical Symptoms (symptoms commonly reported after kidney or liver donation, e.g. numbness at the site of the scar; abdominal bloating)	19	n/a	Verbesey et al. (51), Chan et al. (52), Myaskovsky et al. (53)
Fatigue in the last week	6 weeks, 3 months	Functional Assessment of Chronic Illness Therapy—Fatigue Scale	13	.88	Webster et al. (54)
Pain in the last 24 h	6 weeks, 3 months	Pain Severity Rating Scale from Brief Pain Inventory	1	n/a	Mendoza et al. (55), Cleeland and Ryan (56)
Time to recovery	3 months	Single item concerning how long it had taken to physically recover from surgery	1	n/a	Simmons et al. (34), Switzer et al. (35), DiMartini et al. (57)
No. of unexpected medical problems related to donation	3 months	Medical difficulty items from Checklist of Unexpected Problems Since Donation (e.g. problems undergoing anesthesia, more pain than expected)	5	n/a	Simmons et al. (32), Switzer et al. (35), DiMartini et al. (57)
Postdonation psychological domain					
Depression symptoms	6 weeks, 3 months	Patient Health Questionnaire-9 (PHQ-9)	9	.88	Kroenke et al. (58)
Anxiety symptoms	6 weeks, 3 months	Generalized Anxiety Disorder-7 (GAD-7)	7	.75	Spitzer et al. (59)
Negative feelings about the donation	6 weeks, 3 months	Negative Feelings About Donation Scale (feelings such as sadness at having donated)	4[2]	.72	Simmons et al. (34), Switzer et al. (35), Corley et al. (60)
Family relationship domain					
Quality of relationship with spouse	6 weeks, 3 months	Items from Dyadic Adjustment Scale	9	.98	Spanier (61), Pearlin and Schooler (62)
Quality of relationship with family	6 weeks, 3 months	Intimacy/Conflict scales from the ICPS (Intimacy, Conflict, Parenting Style scale)	13	.87	Noller et al. (63)
No. of unexpected family problems related to donation	3 months	Family difficulty items from Checklist of Unexpected Problems Since Donation (e.g. problems missing important family activities)	7	n/a	Simmons et al. (34), Switzer et al. (35), DiMartini et al. (57)

[1]Measures were selected that had known psychometric properties. See sources cited for information on these properties.
[2]Two additional items were assessed but excluded from the final measure because many subjects said the items were unclear and α was low when they were included; they pertained to feeling relieved that donation had occurred and feeling like they had given up something for nothing in return.

Analyses

Analyses followed the intention-to-treat principle; comparisons were made according to the intervention groups to which subjects were assigned. However, as per RCT reporting guidelines (65), we note that postdonation assessments were not conducted unless subjects underwent donation (see Figure 2) because it is not reasonable to ask subjects about outcomes from a procedure they did not undergo.

Study groups' descriptive characteristics were compared via F or Kruskal–Wallis tests (continuous measures) and chi-square or Fisher's exact tests (categorical measures). Change in ambivalence between T0 and T1 was compared across intervention conditions within a 3 (intervention condition) by 2 (type of PD, kidney vs. liver) analysis of variance (ANOVA). We controlled for type of PD to ensure that any intervention effects were determined independent of any impact of type of (anticipated) donation on outcome. To examine postdonation outcomes, we used mixed effects models with fixed effects for intervention condition (three groups), and type of donation (kidney vs. liver) and the repeated measures factor, time (6 weeks, 3 months postdonation); random effects for subject ID and intercept; and compound symmetry covariance structure for repeated measures on the same subject over time (66,67). Linear models were used for continuous outcomes; linear models with a logit link function were used for dichotomous outcomes (67). Mixed effects models were used because there were one to two observations missing on several outcomes at each timepoint. We could not identify any systematic pattern to the missingness; data were considered to be missing at random.

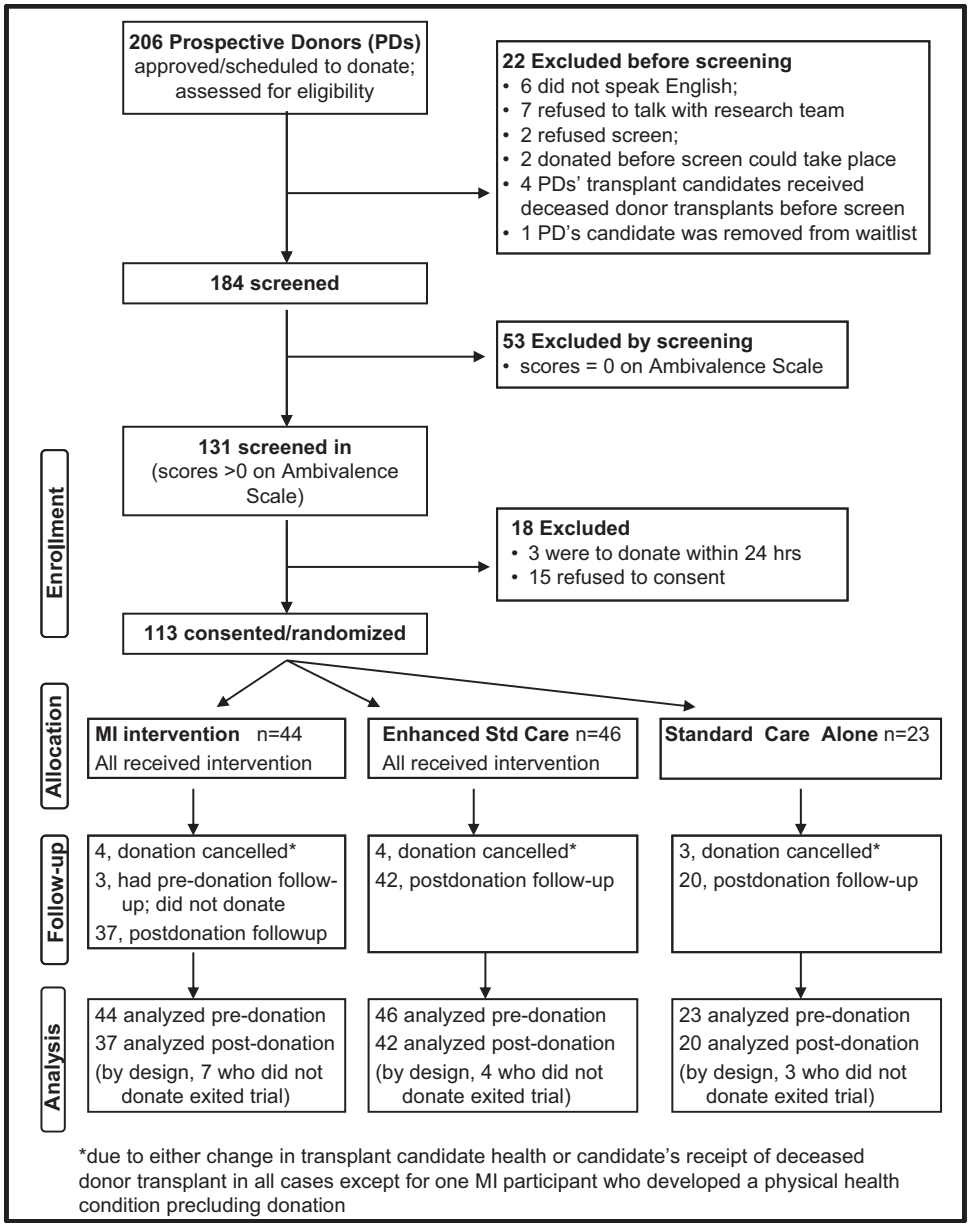

Figure 2: Study flowchart.

Because ours was a Phase II RCT, it was not powered to detect differences between individual pairs of study conditions (68,69). Instead, we sought to establish feasibility and compare the MI group to both other groups combined in order to explore whether there was any ''signal'' suggesting intervention efficacy that might warrant a full-scale trial. Thus, we report omnibus (''main effects'') tests within the ANOVA and mixed models concerning whether the three intervention groups differed, and then planned tests of simple effects (comparing MI to both other groups combined) at each timepoint. Our target sample size was determined by this simple effects focus: power to detect at least a moderately sized difference (e.g. $d \geq 0.50$) (70) between the MI group and both other groups combined, given a targeted sample size of 45 in the MI group and a combined total of 67 in remaining groups, was ~80%.

Results

Feasibility and sample characteristics

Figure 2 shows subject flow. Of 184 PDs screened, 131 (71%) scored >0 on the Ambivalence Scale. The majority of these PDs (n = 113, 87% of those who screened in) were enrolled. Fifteen PDs who refused enrollment predominantly cited lack of time. We could not identify any demographic or donation-related differences between PDs who did and did not enroll.

All subjects received the study condition to which they were assigned (Figure 2). Ninety-eight percent (43/44) of MI subjects and 93% (43/46) of Enhanced Standard Care subjects finished both intervention sessions (reasons for no second session: surgery date moved up; surgery cancelled due to transplant candidate factors). All subjects completed T1 assessments (postintervention). While all PDs were scheduled for surgery, 14 did not donate, most often due to factors beyond PDs' control (noted in Figure 2; three PDs who decided not to donate are discussed below). All subjects who donated completed the postdonation assessments (0% attrition across follow-up).

Table 3 shows sample descriptive characteristics. The sample includes 83 kidney donors and 30 liver donors and is representative of our center's donor population on demographic and donation-related characteristics, with no reliable differences between study intervention groups. Kidney and liver donors were indistinguishable on most demographic and donation-related characteristics (Table 3, footnote 1).

Intervention effects on donation decisions and residual ambivalence

Three individuals in the MI condition reported at T1 that they had decided not to donate (3/44 = 6.8%). No subjects in other groups decided not to donate (0/69; comparison of MI group vs. all other subjects, exact p = 0.057).

At T0, group ambivalence levels were similar: means (SEs) were 2.7 (0.2) for the MI group, 2.8 (0.3) for Enhanced Standard Care and 2.7 (0.4) for Standard Care Only, $F(2,108) = 0.17$, $p = 0.844$), and groups did not differ in variability in ambivalence scores ($F(5,107) = 0.48$, $p = 0.789$). From T0 to T1, the 44 MI subjects' ambivalence declined by an average (SE) of 1.1 (0.2; i.e. ~16% on the 0–7 point scale). Declines for subjects in the Enhanced Standard Care and Standard Care Only groups were smaller, averaging 0.7 (0.2) and 0.5 (0.2), respectively (7–10% on the scale; planned contrast comparing the MI group to remaining groups, $F(1,108) = 3.92$, $p = 0.050$).

Intervention effects on postdonation outcomes

The study groups' distributions on variables in each outcome domain are shown in Table 4, and graphs of the outcome levels for each group at each postdonation timepoint are shown in Figures 3–5. We found significant overall between-group differences in the somatic domain (last column, Table 4). However, our primary focus was on simple effects tests comparing the MI group to both other groups at each timepoint. In the somatic domain, by 3 months postdonation (T3) the MI group had significantly fewer donation-related symptoms (4.3 vs. 6.0 and 6.7 in the other groups; see Table 4 and Figure 3). They were less likely to report any fatigue or any pain, they reported a shorter time to recovery, and they reported fewer unexpected medical problems (Figure 3).

In the psychological domain, the MI group had a significantly lower percentage of subjects with any depression symptoms at 6 weeks postdonation, although this effect was not maintained by 3 months (Figure 4). However, the MI group had a significantly lower percentage of subjects with any anxiety symptoms at 3 months postdonation. In the familial relationship domain, the MI group did not differ from remaining groups on marital or other family relationship quality, but MI subjects reported significantly fewer unexpected donation-related family problems at 3 months postdonation (Figure 5).

Effect sizes are reported in Figures 3–5 (d's for the association of MI intervention group with better scores on continuous outcomes; odds ratios for the likelihood of avoiding adverse outcomes in the MI group vs. other groups on dichotomous variables). The effect sizes for statistically significant effects are modest to moderately large (d's of 0.43–0.49; odds ratios of 3.14–7.70) (70,73).

We included donor type (kidney, liver) in all analyses. There were no large or statistically significant interactions indicating that intervention effects varied by donor type. However, there were independent effects of donor type: liver donors reported significantly more physical symptoms, longer recovery time and higher rates of pain, depressive and anxiety symptoms (all p's < 0.05). There were no significant donor type differences on other pre- or postdonation outcomes (data available from M.A.D.).

Table 3: Demographic, donation-related, and intervention timing characteristics of randomized study subjects

Characteristic[1]	Motivational Interview (N = 44)	Enhanced Standard Care (N = 46)	Standard Care Only (N = 23)	Three-group comparison	
				Test[2]	p-value
Demographic					
Gender, % (n) female	63.6 (28)	58.7 (27)	60.9 (14)	0.23	.891
Age, M (SD)	40.8 (10.7)	41.1 (11.7)	43.7 (11)	0.59	.559
Race					
% (n) European American	90.9 (40)	89.1 (41)	91.3 (21)	—	.974
% (n) African American	4.5 (2)	6.5 (3)	4.3 (1)		
% (n) other	4.5 (2)	4.3 (2)	4.3 (1)		
Education					
% (n) $\leq$ high school	59.1 (26)	50.0 (23)	52.2 (12)	2.44	.656
% (n) college	25.0 (11)	26.1 (12)	17.4 (4)		
% (n) postgraduate	15.9 (7)	23.9 (11)	30.4 (7)		
Marital status, % (n) married	56.8 (25)	54.3 (25)	69.6 (16)	1.54	.464
Employed full time, % (n) yes	72.7 (32)	65.2 (30)	73.9 (17)	0.82	.663
Occupation, % (n) professional	68.2 (30)	56.5 (26)	69.6 (16)	1.75	.417
Donation-related					
Relation to transplant candidate				0.16	.924
% (n) family[3]	75.0 (33)	73.9 (34)	78.3 (18)		
% (n) unrelated	25.0 (11)	26.1 (12)	21.7 (5)		
Type of prospective donor					
% (n) kidney	72.7 (32)	73.9 (34)	73.9 (17)	0.02	.990
% (n) liver	27.3 (12)	26.1 (12)	26.1 (6)		
Postdonation length of hospital stay, days, median (IQR)[4,5]	2 (2–4)	2 (2–5)	2 (2–3)	1.42	.492
Postdonation hospital readmission due to complication, % (n) yes[4]	5.4 (2)	7.1 (3)	5.0 (1)	—	1.000
Postoperative complications occurring during study period, Clavien grade (71,72) [4,6]					
% (n) no complication	75.7 (28)	78.6 (33)	75.0 (15)	—	.991
% (n) Grade 1	18.9 (7)	16.7 (7)	20.0 (4)		
% (n) Grade 2	5.4 (2)	4.8 (2)	5.0 (1)		
Recipient deceased during study follow-up period, % (n) yes	2.7 (1)	0.0 (0)	5.0 (1)	—	.337
Intervention timing, median (IQR)[5]					
Days from intervention to T1 assessment	6 (5–10)	6 (3–12)	—	0.81	.367
Days from intervention to donation[4]	19 (12–25)	17 (9–48)	—	0.02	.894
Days from T1 assessment to donation[4]	5 (2–13)	8 (5–24)	6 (3–18)	5.72	.057

[1]There were no large or significant differences between kidney versus liver donors on variables in this table except that kidney donors were older than liver donors (mean age 43 vs. 35, $t(111) = 3.71$, $p < 0.001$) and kidney donors had a shorter postdonation length of hospital stay (median of 2 days vs. 6 days for liver donors), $\chi^2 = 59.4$, $p < 0.001$. Type of donor was controlled in all outcomes analyses.

[2]$F(2,110)$ for continuous variables; χ^2 (2) for categorical variables; Kruskal–Wallis χ^2 (2) for length of stay and intervention timing variables due to skewed distributions; Fisher's exact test for variables with low expected values in some categories.

[3]includes biologically related and emotionally related family members (e.g. spouses).

[4]Assessed in individuals proceeding to donation, n's of 37, 40 and 20, respectively; see Figure 2.

[5]IQR, interquartile range.

[6]For donors with more than one complication, highest Clavien grade was used. No donors experienced complications above Grade 2.

Table 4: Effects on outcomes in perceived physical health, psychological, and family relationship domains[1]

Outcome variable	Motivational Interview (N = 37)	Enhanced Standard Care (N = 42)	Standard Care Only (N = 20)	3-group difference	
				F	p-value
Physical health and somatic complaints domain					
No. of physical symptoms related to donation, M (SE)				3.76	0.025
T2: 6 weeks post	9.1 (0.6)	9.8 (0.6)	10.9 (1.0)		
T3: 3 months post	4.3 (0.6)*	6.0 (0.6)	6.7 (0.9)		
Any fatigue in the last week, % yes				2.87	0.059
T2: 6 weeks post	88.0	96.4	89.2		
T3: 3 months post	67.4*	90.6	80.7		
Any pain in last 24 h, % yes				3.39	0.036
T2: 6 weeks post	46.4	64.3	60.6		
T3: 3 months post	19.3*	46.7	56.2		
Time to recovery, months, M (SE)				2.22	0.114
T2: 6 weeks post	—	—	—		
T3: 3 months post	1.72 (0.1)*	2.08 (0.1)	2.20 (0.3)		
No. of unexpected medical problems related to donation, M (SE)				2.77	0.068
T2: 6 weeks post	—	—	—		
T3: 3 months post	0.8 (0.3)*	1.6 (0.2)	1.4 (0.3)		
Psychological domain					
Presence of depression symptoms, last 2 weeks, % yes				2.20	0.114
T2: 6 weeks post	5.6*	35.5	41.5		
T3: 3 months post	18.8	23.1	17.2		
Presence of anxiety symptoms, last 2 weeks, % yes				1.21	0.301
T2: 6 weeks post	24.5	28.0	25.0		
T3: 3 months post	14.2*	37.2	34.7		
Have negative feelings about the donation, % yes				1.12	0.328
T2: 6 weeks post	16.2	9.0	41.5		
T3: 3 months post	16.2	14.2	15.1		
Family relationship domain					
Relationship quality, (nonrecipient) spouse, M (SE) (1 = low, 5 = high)[2]				1.18	0.093
T2: 6 weeks post	4.54 (0.1)	4.61 (0.1)	4.68 (0.2)		
T3: 3 months post	4.49 (0.1)	4.56 (0.1)	4.66 (0.2)		
Family relationship quality, M (SE) (1 = low, 6 = high)[2]				0.33	0.721
T2: 6 weeks post	4.98 (0.1)	4.99 (0.1)	5.19 (0.2)		
T3: 3 months post	4.98 (0.1)	4.99 (0.1)	5.02 (0.2)		
No. of unexpected family problems related to donation, M (SE)				2.17	0.120
T2: 6 weeks post	—	—	—		
T3: 3 months post	0.3* (0.1)	0.9 (0.1)	0.7 (0.2)		

[1]We controlled for type of donor (kidney, liver) in all analyses.
[2]This variable was log transformed prior to analyses to reduce skewness in its distribution; means on the original scale are shown in order to facilitate interpretation.
*$p < 0.05$ comparing MI to both other groups combined at a given time point. See Figures 3–5 for test statistics, p-values and effect sizes.

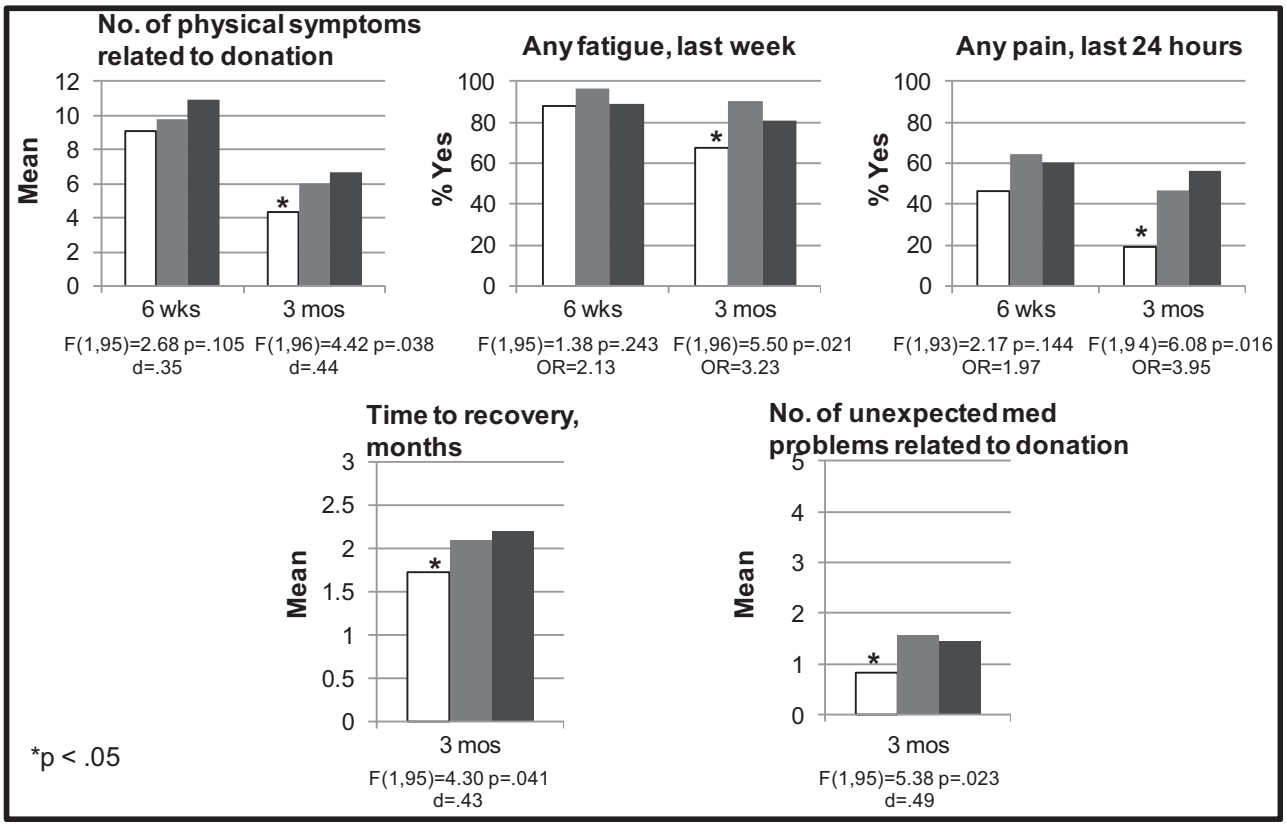

Figure 3: Effects of MI intervention on somatic outcomes domain at 6 weeks and 3 months postdonation. Each F compares MI subjects to all other subjects. F from linear model for continuous variables (effect size, d); F from general linear model with logit link function for dichotomous variables (effect size, odds ratio, OR). □ MI; ■ enhanced standard care; ■ standard care only.

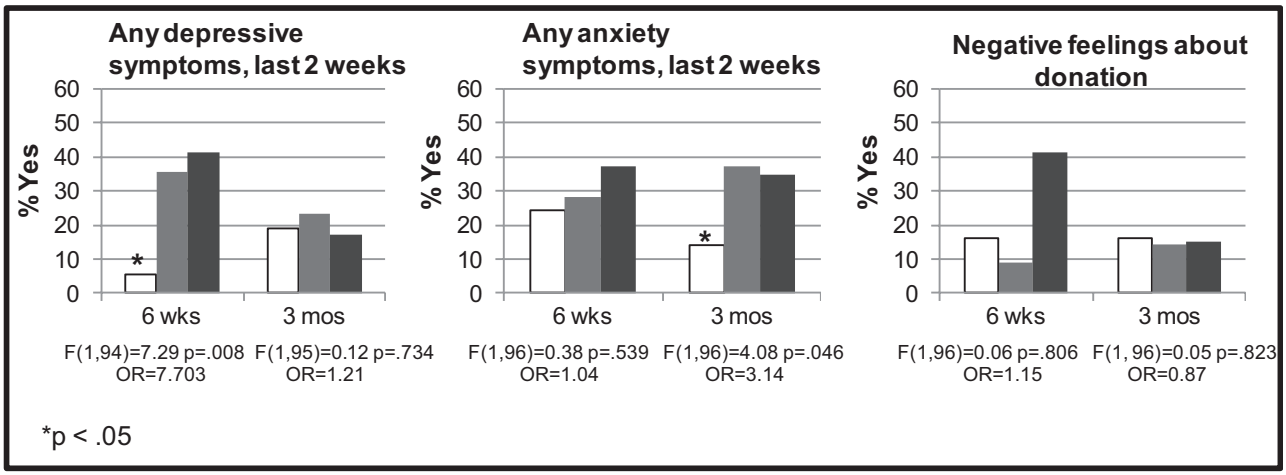

Figure 4: Effects of MI intervention on psychological outcomes domain at 6 weeks and 3 months postdonation. Each F compares MI subjects to all other subjects. F from general linear model with logit link function for these dichotomous variables (effect size, odds ratio, OR). □ MI; ■ enhanced standard care; ■ standard care only.

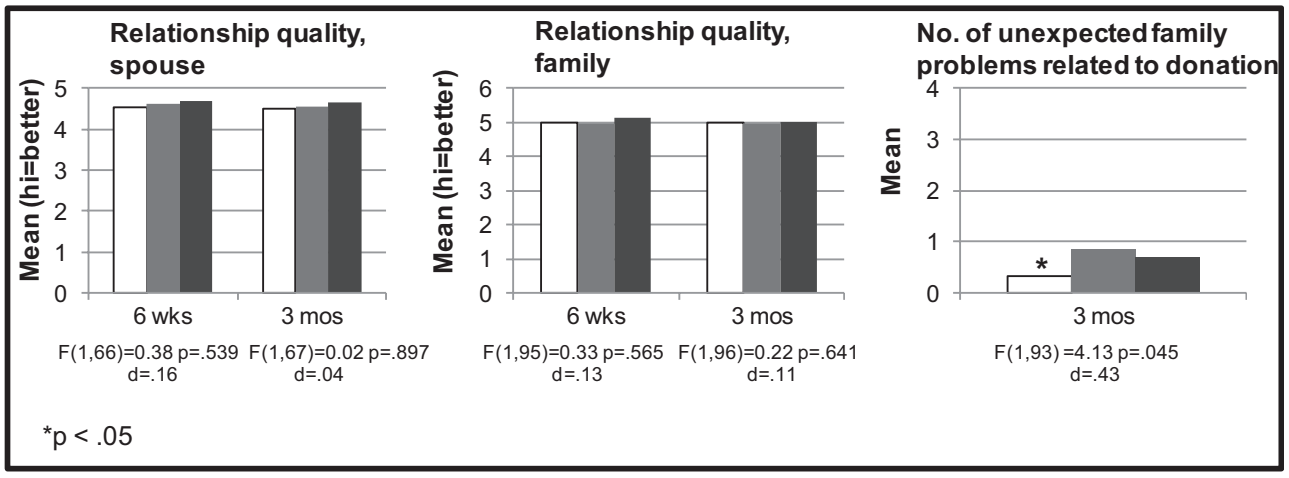

Figure 5: Effects of MI intervention on family relationship domain at 6 weeks and 3 months postdonation. Each F compares MI subjects to all other subjects. F from linear model for continuous variable (effect size, d); F from general linear model with logit link function for dichotomous variables (effect size, odds ratio, OR). □ MI; ■ enhanced standard care; ■ standard care only.

Discussion

The mandate to promote living donors' safety has led not only to careful evaluation protocols to select them, but to guidelines and policies for monitoring postdonation health status (6,8,9). Postdonation monitoring may allow for timely intervention should medical or psychosocial problems be revealed. However, efforts to avert problems may be more efficient than deploying postdonation interventions, especially if prevention efforts are targeted to PDs at heightened risk. This ''selective'' prevention approach (29,30,74) is also likely to be more practical and cost-effective than ''universal'' prevention, in which even individuals with no risk factors receive preventive interventions (30). Although one might argue that PDs at risk for poor psychosocial outcomes should not donate, use of effective preventive interventions could allow them to donate more safely and thus help to ensure that living donation remains an option for transplant candidates who might otherwise be unable to receive transplants.

Our results suggest that a brief intervention offered to an at-risk population—PDs with residual ambivalence about donation—may be useful for prevention purposes. Such feelings of lingering hesitation and uncertainty are common in PDs and, similar to rates in other studies (11), we observed that 71% of the PDs we screened evidenced some degree of residual ambivalence.

Because the timeline between donor approval and surgery may be brief, feasibility concerns arise in mounting a preventive intervention in this population. MI-based interventions are usually brief and can be conducted effectively by telephone (44,45); both factors are likely to have contributed to our success in completing the intervention and study assessments before donation surgery. Equally striking, we had no attrition across postdonation assessments. However, some PDs did not donate due to factors beyond their control (e.g. transplant candidate health changes). We had not expected this to happen as often as it did; a full-scale RCT would need to consider this in estimating sample size needs.

Concerning intervention effects, subjects receiving the MI intervention showed reduced ambivalence relative to the comparison groups. We believed that, if ambivalence was resolved, PDs would be better able to reach their own final choice regarding whether to proceed with donation. The fact that three PDs receiving the MI intervention ultimately decided against donation, while no PDs in other study groups changed their minds, suggests that the MI intervention was, as designed, helping PDs to reach decisions that they personally judged to be best. This effect demands more thorough evaluation in a larger trial. Nevertheless, we view the result as a positive: there is strong sentiment in the transplant community that no one should donate if they are unsure it is the right choice.

An intervention that helps PDs to feel they have made the right choice, and to feel at peace with that choice, seems to have potential: it may explain why subjects in the MI group who did donate (the vast majority) appeared to have more favorable postdonation outcomes than other subjects. It is well-known that individuals with concerns and negative expectations about undergoing surgical procedures often report negative psychological reactions and somatic problems after surgery (75). In the context of living donation, where donors experience no direct medical benefit from surgery, the importance of resolving any lingering concerns, doubts and worries may be even further heightened.

These components of residual ambivalence may color donors' experiences of the donation and recovery even in the first several days after surgery (34); this very early response may ultimately contribute to poorer outcomes (34). It has been recommended that PDs with such concerns before donation receive additional attention and support from the donor team in order to promote optimal postdonation outcomes (31,76). Our intervention provided uniquely tailored support in this regard.

In terms of outcomes, the MI intervention appeared most potent for reducing risk for somatic complaints by 3 months postdonation. Donors in the MI group reported fewer symptoms, lower rates of fatigue and pain, a quicker recovery and fewer unexpected medical problems. They were less likely to have anxiety symptoms and reported fewer unexpected donation-related family problems at 3 months postdonation. The sizes of these effects were generally moderate. Of importance, for dichotomous variables, for example, these effects translate into numbers needed to treat (NNT, the number of persons needing to receive a preventive intervention in order to avoid one new case of the adverse outcome) (77) of between three and five. NNTs of 3–5 indicate clinical effectiveness and hence clinically important impact (78,79). While our results cannot be used to estimate effect sizes likely in a full-scale RCT (68,69), they suggest we observed a sufficient ''signal'' regarding intervention efficacy to warrant additional evaluation (69).

Key study limitations are, first, its small size and single-center focus. While these limitations are acceptable for Phase II work, a full-scale trial would require a larger sample, from multiple sites, in order to determine generalizability and to be powered to examine mechanisms accounting for intervention effects. Second, we found relatively little impact of the MI intervention on the family relationship domain, due either to our choice of measures or to a true absence of effects. However, it seems premature to exclude this domain from even exploratory consideration in a future trial, since family relationship difficulties have been reported in donors (11). Third, we did not assess psychosocial outcomes at baseline in order to determine that the groups were equivalent on these variables before the intervention or donation. The fact that subjects were randomized reduces the likelihood of such imbalances. Moreover, many of our outcomes were donation-specific (e.g. somatic complaints related to the surgery; unexpected donation-related problems) and logically could not be assessed predonation. Nevertheless, for other factors such as psychological symptoms, future work should examine change from baseline rather than postdonation levels alone. A fourth limitation is that our postdonation follow-up was brief. Whether effects would be maintained beyond 3 months is unknown. Fifth, the study groups may have differed on unassessed background characteristics (e.g. recipient outcomes other than survival status) that could have served as confounding factors.

Despite these limitations, the study provides the first empirical evaluation of a preventive intervention designed to avert poor psychosocial outcomes in living donors. Feasibility and efficacy results suggest that the intervention merits testing in a larger, multisite trial. The trial's design should take into account uncontrollable factors that affect subjects' progress toward donation (e.g. changes in transplant candidates' status), and it should include a sufficiently long follow-up period to determine whether any intervention effects are maintained. We are currently designing such a trial, with follow-up through 1 year postdonation. If a full-scale trial demonstrates reliable effects, issues of dissemination into routine clinical care would become prominent. These issues would pertain, for example, to resources needed and associated costs. Given its focus on ambivalence and on giving PDs an opportunity to reflect on their reasons for donating, the intervention may logically fit within activities performed by the independent donor advocate (IDA). IDAs come from a wide variety of disciplines; it is thus an asset that MI-based interventions' effects are not influenced by interventionist discipline (e.g. nursing, medicine, psychology, social work) (45). Finally, the brevity of our intervention serves to increase its potential for cost-effectiveness and potential uptake by living donor programs.

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Disclosures

The authors of this manuscript have no conflicts of interest to disclose as described by the *American Journal of Transplantation*.

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