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The feasibility of a group stress management Liver SMART intervention for patients with end-stage liver disease: A pilot study

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Abstract

Objectives—Structured, empirically supported psychological interventions are lacking for patients who require organ transplantation. This Stage IA psychotherapy development project developed and tested the feasibility, acceptability, tolerability, and preliminary efficacy of an 8-week group cognitive behavioral stress management intervention adapted for patients with end-stage liver disease awaiting liver transplantation.

Methods—Twenty-nine English-speaking United Network for Organ Sharing registered patients with end-stage liver disease from a single transplantation center enrolled in the 8-week group cognitive behavioral Stress Management and Relaxation Training, Liver SMART, intervention adapted for patients with end-stage liver disease. Patients completed pre- and post-intervention surveys that included the Beck Depression Inventory-II and the Beck Anxiety Inventory. Feasibility, acceptability, tolerability, and preliminary efficacy were assessed.

Results—Attendance rate was 69.40%. The intervention was rated as “good” to “excellent” by 100% of participants who completed the post-intervention survey in teaching them new skills to relax and to cope with stress, and by 94.12% of participants in helping them feel supported while waiting for a liver transplant. No adverse events were recorded over the course of treatment. Attrition was 13.79%. Anxious and depressive symptoms were not statistically different after the intervention.

Significance of Results—The Liver SMART intervention is feasible, acceptable, and tolerable to end-stage liver disease patients within a transplant clinic setting. Anxious and depressive

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symptoms remained stable post-intervention. Randomized controlled trials are needed to study the intervention's effectiveness in this population.

Keywords

liver transplantation; psychotherapy; quality of life; pilot projects; feasibility studies

Introduction

Liver transplantation is the standard of care for patients with end-stage liver disease but donor organ availability remains insufficiently low to meet the rising demand (Kim et al., 2017). Waiting periods for liver transplantation can last up to 3 years or longer (Kim et al., 2017), during which time patients confront poor physical quality of life (Derck et al., 2015), deteriorating health (Lai, 2016), and mortality. In the face of challenges to their physical health, many patients report anxiety around fears of transplant surgery, death, and the overall uncertainty of living with a life-threatening chronic illness (Santos et al., 2012); this pre-transplant anxiety predicts higher post-transplant anxiety and lower post-transplant quality of life (Miller et al., 2013). Up to 80% of liver transplant candidates may experience depression (Mohamed et al., 2014), which predicts higher post-transplant depression (Miller et al., 2013) and is associated with post-transplant physical health outcomes including longer transplant length of hospital stay, discharge to a location other than home, and mortality (Rogal et al., 2016).

Despite significant advances in the basic sciences related to immunosuppressant therapies and transplant medicine, relatively little attention has been placed on the development of psychosocial interventions to address the psychological aspects of waiting for organ transplantation. Therefore, this pilot study sought to address the dearth of psychosocial interventions for end-stage liver disease patients by testing the feasibility, acceptability, and tolerability of an 8-week group-based cognitive behavioral stress management intervention intended to alleviate stress-related symptoms of depression and anxiety for patients diagnosed with end-stage liver disease and awaiting liver transplant.

Few studies to date have tested the feasibility or efficacy of psychosocial interventions tailored specifically to patients waitlisted for liver transplantation. One group outside of the United States (Georgiou et al., 2003) demonstrated the feasibility of a pre-transplantation psychosocial intervention, and another group found initial evidence that a coping skills group can enhance coping and decrease anxiety and depression in patients awaiting liver or kidney transplantation (Craig et al., 2017). One randomized controlled trial (Sharif et al., 2005) indicated that a psycho-educational intervention enhances quality of life in patients awaiting liver transplantation. Within the United States, a randomized controlled trial of a telephone uncertainty self-management intervention did not find that the intervention group differed from the control group on outcomes including anxiety, depression, and quality of life (Bailey et al., 2017). Given the preliminary evidence from outside the United States that live psychosocial intervention groups are feasible and efficacious, research is needed to test whether a live group intervention is feasible and acceptable within the United States healthcare system.

Cognitive behavioral stress management was designed specifically to empower groups of medically ill patients with tools to regulate their mood and access the forms of social support they need (Antoni, 2003). Over the course of several weekly sessions, patients are taught a variety of relaxation techniques, learn to identify and restructure unhelpful thoughts that lead to negative emotions and maladaptive behaviors, and engage in discussion of interpersonal communication topics. Randomized controlled trials have found that women diagnosed with non-metastatic breast cancer randomized to a 10-week group cognitive behavioral stress management intervention reported greater reductions in intrusive thoughts about breast cancer, anxiety, and negative affect one year post-intervention as compared with women in a control condition (Antoni et al., 2006). Furthermore, they reported lower depressive symptoms and higher satisfaction with physical and emotional quality of life than women in a control condition eleven years after the intervention commenced (Stagl et al., 2015). Even a shorter 5-week intervention enhanced emotional well-being and decreased intrusive thoughts about cancer post-intervention (Gudenkauf et al., 2015).

We hypothesized that an 8-session Liver Stress Management and Relaxation Training (Liver SMART) cognitive behavioral stress management group intervention program designed to decrease stress-related symptoms and increase social support would be feasible, acceptable, and tolerable for wait-listed patients with end-stage liver disease and would decrease depressive and anxious symptoms. We adapted sessions from existing coping skills manuals that were relevant for targeting the specific stressors and symptoms experienced by patients with end-stage liver disease and examined the feasibility, acceptability, tolerability, and preliminary efficacy of Liver SMART within a hospital-based transplant center.

Methods

Participants

The study included a subsample of participants from a prior psychosocial assessment of 125 patients with end-stage liver disease who were recruited during routine clinic appointments and/or by telephone as previously described (Fernandez et al., 2015; Amoyal et al., 2016). All patients in the original study were 18 years or older, spoke English fluently, and were wait-listed with the United Network for Organ Sharing for liver transplantation at Yale-New Haven Transplantation Center. Patients had been excluded if they lacked fluency in English, or if the severity of their disease impeded participation in the assessment and intervention.

Procedures

This study was a Stage IA (Rounsaville et al., 2001; Carroll & Nuro, 2002) pilot psychotherapy development project organized around psychotherapy development as well as feasibility, acceptability, and tolerability testing of the proposed intervention. The project was approved by the Yale University School of Medicine's Human Investigation Committee (#0807004087, Approval Date 11 August 2008) and all participants were required to provide informed consent prior to their participation in the study. The project was conducted in accordance with the Declaration of Helsinki. All assessment information was collected by supervised research assistants from Yale University School of Medicine's Department of Psychiatry between 2008 and 2011. Each Liver SMART group consisted of 8 weekly

sessions lasting 60 minutes. Five groups were facilitated, each containing between 2 and 6 participants. Groups were facilitated face-to-face by therapists with prior training and experience in behavioral medicine and cognitive behavioral therapy, including a licensed clinical psychologist and 3 supervised pre-doctoral psychology interns. Participants did not receive compensation for their participation.

Measures

Demographic and medical variables—Demographic variables including age, gender, race/ethnicity, number of children, marital status, occupational status, and household income were self-reported via a demographic questionnaire. Medical data including disease etiology and severity, functional impairment, and body mass index were recorded via medical record review.

Psychological Measures—Psychiatric symptom severity was assessed at study entry and post-intervention with the Beck Depression Inventory – II (Beck et al., 1996) and the Beck Anxiety Inventory (Beck et al., 1988). Internal consistency of the questionnaires was adequate in this sample as indicated by Cronbach's alpha (α): Beck Depression Inventory – II $\alpha = .91$; Beck Anxiety Inventory $\alpha = .90$.

Feasibility—Feasibility was operationalized as the rate of enrollment and as the rate of attendance, which was calculated as the average percentage of sessions attended out of 8. Self-reported reasons for not attending were recorded either when the participant informed the clinician that they would not attend a session, or when a research assistant called the participant after a missed session.

Acceptability—An anonymous survey written by the principal investigator was administered at the last session of the intervention that assessed on a scale of “Poor” to “Excellent” how helpful patients found the intervention to be in teaching them relaxation skills and coping skills, and making them feeling supported. The questionnaire also solicited qualitative responses regarding what participants found to be most and least helpful about the intervention, and what additional topics participants wished had been included in the intervention.

Tolerability—The tolerability of the intervention was operationalized as the presence of adverse events reported to the Human Investigation Committee, and as dropout rate calculated as the percentage of patients who informed the study team that they were no longer participating in the intervention.

Liver SMART intervention

The Liver SMART program adapted the Stress Management and Relaxation Training for women with breast cancer (B-SMART) program (Antoni, 2003) to the needs of patients with end-stage liver disease. The overarching therapeutic model of the group stress management intervention applied cognitive behavioral therapy, including relaxation training, to provide participants with information and skills to monitor and cope with physical and emotional stress and to reduce adverse stress-related symptoms of depression and anxiety.

Development of the Liver SMART group intervention was an ongoing iterative process that incorporated data collected through an initial needs assessment as well as participant feedback/data referable to the model's feasibility and efficacy (Carroll & Nuro, 2002) and therapist experience.

The preliminary version of the Liver SMART intervention consisted of the modules displayed in Table 1. Each session incorporated discussion, support, homework review, and agenda setting (10-15 minutes), coping skills training and psycho-education (20-25 minutes), relaxation training (10 minutes), and homework planning (5-10 minutes). Patients were exposed to a variety of relaxation techniques. After an introductory session, three sessions taught patients cognitive-behavioral therapy-based stress awareness and coping techniques to help with the identification and restructuring of unhelpful thoughts that contribute to negative emotions and maladaptive behaviors. The next 3 sessions focused on fostering interpersonal communication through engaging in discussion of social support, assertiveness, and anger management. Throughout these modules, patients learned to identify the types of support they lack, overcome barriers to requesting support from members of their social networks, and navigate disagreements with support sources. Finally, the last session provided healthy lifestyle information. Each week patients were asked to complete a homework assignment that included practicing behavioral relaxation skills, cognitive reframing skills, interpersonal effectiveness skills, and daily stress ratings to encourage self-monitoring and self-assessment. Patients were provided with a printed intervention manual and a CD of recorded relaxation exercises.

Data analysis

The sample was characterized according to demographic and medical variables using descriptive statistics including means, standard deviations, and frequencies. Chi square tests and one-way analysis of variance were used to test whether those who participated in the intervention differed from those who did not on demographic, medical, and psychiatric variables. Frequencies were also used to characterize enrollment rate, attendance rate, prevalence of reasons for not attending study sessions, prevalence of acceptability ratings of the intervention, number of adverse events, and dropout rate. Paired samples t-tests tested whether Beck Depression Inventory – II and Beck Anxiety Inventory scores changed from pre-intervention to post-intervention. All variables were checked for normal distribution (skewness < 3.0, kurtosis < 8.0; Kline, 2011) prior to analysis.

Results

Sample characterization

Table 2 shows the demographic, psychological, and medical characteristics of the 29 participants who consented to this pilot study and the 120 participants invited to participate. Participants who received the intervention were predominately white, married, and on disability. Liver disease etiology was primarily due to Hepatitis C (55.2%). On average, Model for End-Stage Liver Disease score was 13.41 (SD=3.75). Mean Beck Depression Inventory – II score was 13.55 (SD=11.10), indicating minimal depression, but ranged from

minimal (0), to severe depression (39). Mean Beck Anxiety Inventory score was 10.12 (SD=10.02), indicating mild anxiety, and ranged from minimal (0), to severe anxiety (36).

Patients who enrolled in the intervention did not differ from those who declined to participate on demographic, medical, or psychiatric variables including age, gender, race/ethnicity, number of children, marital status, occupational status, income, liver disease etiology, Hepatocellular Carcinoma status, disease severity, functional impairment, body mass index, Beck Depression Inventory-II score, or Beck Anxiety Inventory score (all p s > .05).

Feasibility

Of the 120 patients invited to participate in the intervention, 29 (24.2%) enrolled. Participants attended on average 5.6 of the program's 8 sessions, and the overall attendance rate was 69.40%. Nearly half of all absences (48.48%) occurred because the participant reported feeling too sick to attend the session. Nearly one-fifth (19.70%) of sessions missed were attributable to participants who dropped out. Participants also reported that they had missed sessions due to conflicting appointments (10.61%), lack of transportation (7.04%), being hospitalized (6.06%), weather (4.55%), going on vacation (2.82%), and other unspecified reasons (7.04%).

Acceptability

Out of the 17 participants that completed the post-intervention survey, 12 (70.59%) group participants reported that the intervention was "excellent" in its helpfulness in teaching new skills to relax, while 5 (29.41%) rated it as "good." With regard to how helpful the intervention was in teaching new skills to cope with stress in life, 9 (52.94%) rated it as "excellent" and 8 (47.06%) rated it as "good." Eight (47.06%) participants reported that the intervention was "excellent" in helping them feel more supported throughout the process of waiting for a liver transplant, 8 (47.06%) reported that it was "good," and 1 participant (5.88%) reported that it was "average."

Qualitatively, 10 (58.82%) participants indicated that the relaxation exercises were the most helpful elements of the treatment. Eleven participants indicated that sharing with and listening to other group members coping with liver transplant was the most helpful element of the treatment. Seven participants stated that learning coping mechanisms for stress and worries was most helpful. One participant reported that learning to ask for help was most helpful, and another reported that learning to identify emotions, behaviors, and thoughts was most helpful.

One participant reported that the homework was not helpful and one reported that daily rating forms were not helpful.

With regard to what additional topics participants would have liked to address during the intervention, 4 participants stated that they would have liked to receive more medical information on liver transplantation. Of note, 5 participants expressed that they would have preferred longer sessions, and 1 participant requested a post-transplant psychosocial intervention.

Tolerability

No adverse events that met criteria for reporting to the Human Investigation Committee occurred over the course of the intervention. Four participants (13.79%) dropped out of the study although the reasons were not recorded.

Preliminary Efficacy

A total of 17 participants completed the BAI and BDI after the intervention. Pre-intervention symptoms of depression ($M = 13.53$, $SD = 10.58$) did not differ significantly from post-intervention symptoms ($M = 9.87$, $SD = 2.40$), [$t(16) = 1.456$, $p = 0.165$]. Pre-intervention levels of anxiety ($M = 11.53$, $SD = 10.42$) did not differ from post-intervention levels ($M = 12.53$, $SD = 10.03$), [$t(16) = -0.601$, $p = 0.557$].

Discussion

Conclusions

This cognitive behavioral stress management group intervention was feasible, acceptable, and tolerable to a sample of participants with end-stage liver disease awaiting liver transplantation who were largely similar demographically to the national norms for patients awaiting liver transplantation at the time the study was conducted (Kim et al., 2013). The need for psychological intervention in this medical population has been previously reported (Goetzmann et al., 2006), and clinically significant depressive and anxious symptoms were documented in this sample. Therefore, intervention components included specifically targeted psychosocial issues that have been previously reported in end-stage liver disease patients, including elevated depression and anxiety.

The percentage of patients invited to participate that began the intervention was comparable to the percentage of patients randomized in another study of end-stage liver disease patients (Bailey et al., 2017). It was also higher than the 19% enrollment rate in a pilot randomized controlled psychotherapy trial for patients with advanced cancer, a medical population that has been highly studied with regard to psychosocial intervention (Breitbart et al., 2012). Attendance was slightly lower than in another psychosocial intervention study with end-stage liver disease patients (Bailey et al., 2017). The discrepancy in attendance may be attributable to the delivery method, since the other intervention was carried out via telephone thus eliminating some barriers to attendance, such as lack of transportation. Furthermore, that study provided monetary compensation for participating, which may have enhanced motivation to attend sessions and complete the intervention. The majority of patients reported that the group intervention helped them learn to relax, cope with stress, and feel supported. No adverse events were reported, and the 13.79% attrition was lower than rates documented in other psychotherapy trials of patients with advanced medical illness (Applebaum et al., 2012).

Adaptations made to the B-SMART manual during the development of LiverSMART may have affected the feasibility, acceptability, and tolerability of the intervention. Although B-SMART is conducted during 10 sessions lasting 2 hours, LiverSMART was shortened to consist of 8 sessions lasting 1 hour each. In light of the fatigue reported by a majority of

patients with ESLD (Hansen et al., 2015), fewer and shorter sessions may have been easier for patients to commit to and attend, thereby enhancing enrollment and attendance (feasibility) while maintaining low drop-out (tolerability). The addition of a Healthy Living module to LiverSMART that provided dietary and medication adherence information specifically tailored to liver disease may also have enhanced feasibility and tolerability by promoting buy-in and engagement.

At the same time, condensing the intervention and substituting Healthy Living content for B-SMART session material may have negatively impacted LiverSMART's acceptability. Reducing the number and duration of sessions while adding new material required removal of some B-SMART exercises and also decreased the amount of time in which participants could get to know other group members and clinicians. It is possible that if participants had been given more opportunity to practice relaxation and coping skills and cultivate interpersonal relationships, they would have rated their mastery of relaxation and coping skills and their perceptions of support as higher.

Preliminary tests of efficacy did not reveal statistically significant changes in anxious or depressive symptoms pre- to post-intervention. However, this pilot study was underpowered to detect an effect given the small sample size. Additionally, the design did not include a control group. It is possible that while anxiety and depressive symptoms remained stable in the participants receiving cognitive behavioral stress management, symptoms would have worsened (Corruble et al., 2010) in control participants due to increasing stress associated with lengthening duration of time on the waitlist (Silva et al., 2014). Another possible explanation for the lack of significant effects is that there was no distress level cutoff required for inclusion. Participants reported only minimal depression and mild anxiety on average, and it is possible that LiverSMART would decrease symptom levels for patients reporting higher baseline psychological distress.

Strengths and limitations

This manuscript represents the first study in the United States to test the feasibility, acceptability, tolerability, and preliminary efficacy of a live evidence-based group stress management intervention tailored to the psychosocial needs of patients with end-stage liver disease awaiting liver transplantation. Of note, clinical psychology trainees were able to conduct the intervention, which suggests a potentially cost effective mechanism for facilitating the groups, thus enhancing the intervention's potential to be widely and rapidly disseminated to transplant clinics in academic health centers.

Some limitations of this research should be taken into account when interpreting the findings. First, the sample size was small, therefore the results may not be representative of the greater population of patients awaiting liver transplantation. However, small sample size is typical in feasibility studies (Tickle-Degnen, 2013), and it is notable that the attrition rate was similar to that of prior studies in this population that provided financial incentives for participation. Some limitations to external validity and generalizability should also be considered. The data analyzed in this study were collected 6 years ago and advances in medical treatment (Kim et al., 2017) since then may have altered the demographic and medical characteristics of transplant waiting lists. Follow-up ratings of the intervention and

symptom severity are missing for almost half of the participants, and it is unknown whether they are missing at random or if those participants had a less positive experience, biasing the data towards positive evaluations and lower symptom levels. Additionally, data detailing specific reasons that some patients declined to participate in the intervention are missing, although analyses indicate that those who enrolled in the intervention did not differ on demographic or medical variables from those who declined. Lastly, the generalizability of the results to ethnically and racially diverse samples may be limited since participants were primarily non-Hispanic white, consistent with the demographics of waitlisted liver transplant patients in the United States at the time the study was conducted (Kim et al., 2012). Despite these limitations, publication and dissemination of these findings is justified given the paucity of psychosocial intervention research in patients with end-stage liver disease awaiting liver transplant.

Implications and future directions

Although structured, empirically supported psychosocial interventions are lacking for patients who require liver transplantation, our findings suggest that the Liver SMART intervention is feasible, acceptable, and tolerable within a transplant clinic setting. Several patients actually requested more time in the intervention, therefore future iterations of Liver SMART could include longer sessions or could transition into a post-transplant psychosocial intervention group (Ordin & Karayurt, 2016), possibly with booster sessions. Alternative methods of intervention delivery, such as via telephone or video, should also be tested given that feeling too sick to attend and lack of transportation were commonly reported barriers to attendance, and given that cognitive behavioral stress management has successfully been delivered via telephone to other medical populations (Hall et al., 2017). Future randomized controlled trials with larger and more diverse sample sizes are needed to study the intervention's efficacy at reducing psychological distress and enhancing quality of life in this patient population both before and after liver transplantation.

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Table 1

Session Modules for Liver SMART Program.

Session	Module	Description	Relaxation Exercise
1	Introduction	Orientation to treatment model, structure, purpose; rapport building; participant introductions.	Progressive Muscle Relaxation
2	Stress & Awareness	Introduction to physical stress response and biopsychosocial model of stress and depression.	Deep Breathing
3	Automatic Thoughts	Introduction to self-talk and self-awareness; relationship between thoughts, feelings, and behavior; cognitive reframing; mindfulness.	Mindfulness
4	Coping Strategies	Introduction to problem-solving approaches; problem-focused and emotion-focused coping; coping with uncertainty and acceptance.	Healing and Well-Being
5	Social Support	Introduction to physical activity and mood; social support; faith; barriers to social engagement; education about community resources.	Color Meditation
6	Anger	Introduction to anger and anger management approaches referable to awareness, attitudes about anger, healthy expression of anger, and understanding unhealthy anger.	In With the Good, Out With the Bad
7	Assertiveness	Introduction to assertiveness training; passive versus aggressive communication; characteristics of assertive communication; asking for help.	Mindful Breathing
8	Building a Healthy Lifestyle	Review of healthy lifestyle habits referable to diet, exercise and sleep; review of medication adherence, mind-body connection in liver disease; group wrap-up and feedback.	Mindful Eating

Table 2

Demographic, medical, and psychological characteristics of the intervention subsample (N = 29) and the full sample (N=120).

Patient Characteristic	Intervention subsample (N=29)		Full Sample (N=120)	
	Mean (SD)	Range	Mean (SD)	Range
<i>Sociodemographics</i>				
Age	55.07 (7.24)	43.00–69.00	56.0 (8.71)	27.0–76.0
Gender				
Male	21 (72.4)	--	73 (60.8)	
Female	8 (27.6)	--	47 (39.2)	
Race/Ethnicity				
White	23 (79.3)	--	91 (75.8)	
Black	2 (6.9)	--	12 (10.0)	
Hispanic	1 (3.4)	--	11 (9.2)	
American Indian/Alaskan Native	1 (3.4)	--	1 (0.08)	
Other	1 (3.4)	--	3 (2.5)	
Unknown	1 (3.4)	--	2 (1.6)	
Children	1.72 (1.93)	0–9	1.93 (1.57)	0 – 9
Marital Status				
Married or Cohabiting	11 (37.9)	--	61 (50.8)	
Separated	1 (3.4)	--	4 (3.3)	
Divorced	11 (37.9)	--	29 (24.2)	
Widowed	1 (3.4)	--	5 (4.2)	
Single	5 (17.2)	--	19 (15.8)	
Occupational Status				
Full-time	5 (17.2)	--	20 (16.7)	
Part-time	1 (3.4)	--	5 (4.2)	
Unemployed	7 (24.1)	--	34 (28.3)	
Disability	16 (55.2)	--	59 (49.2)	
Household Income ^a				
<5,000	2 (6.9)	--	6 (5.0)	
5,000–19,999	7 (24.1)	--	26 (21.7)	
20,000–34,999	6 (20.7)	--	19 (15.8)	
35,000–49,999	3 (10.3)	--	12 (10.0)	
50,000–64,999	1 (3.4)	--	8 (6.7)	
65,000–89,999	5 (17.2)	--	10 (8.3)	
90,000–119,999	4 (13.8)	--	13 (10.8)	
120,000–150,000	1 (3.4)	--	5 (4.2)	

Patient Characteristic	Intervention subsample (N=29)		Full Sample (N=120)	
	Mean (SD)	Range	Mean (SD)	Range
<i>Medical Status</i>				
Liver Disease Etiology				
Hepatitis C Virus	16 (55.2)	--	62 (51.7)	
Alcoholic Liver Disease	5 (17.2)	--	18 (15.0)	
Hepatocellular Carcinoma alone ^b	1 (3.4)	--	2 (1.7)	
Nonalcoholic Steatohepatitis	2 (6.9)	--	11 (9.2)	
Other ^c	5 (17.2)	--	26 (21.7)	
Hepatocellular Carcinoma Status				
Yes	7 (24.1)	--	30 (25.0)	
No	22 (75.9)	--	89 (74.2)	
Disease Severity				
Model for End-Stage Liver Disease Score	13.41 (3.75)	6.00–23.00	12.5 (4.47)	6.0–26.0
Karnofsky	0.85 (0.09)	0.60–1.00	85.0 (9.0)	40.0–100.0
Body Mass Index	32.30 (5.69)	22.00–42.00		
<i>Psychiatric Status</i>				
Psychological Symptom Severity				
Beck Depression Inventory-II	13.55 (11.10)	0.00–39.00	11.74 (9.38)	0.00–40.00
Beck Anxiety Inventory	10.12 (10.02)	0.00–36.00	10.47 (11.80)	0.00–57.00

Note: SD = Standard Deviation.

^aIncome in United States dollars.

^bGiannini et al., 2013.

^cOther diagnoses include genetic, metabolic, autoimmune, and unknown etiologies of liver disease.