

Evaluation of the Pathways for Survivors program to address breast cancer survivorship associated distress

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Abstract

Purpose: Breast cancer patients not infrequently experience escalation of anxiety after completing curative treatment. This study evaluated the acceptability and psychological impact of a one-day workshop emphasizing behavioral strategies involving intention and self-efficacy.

Methods: Breast cancer survivors attending a one-day Pathways for Survivors workshop, provided feedback, and completed electronic quality of life (QOL) questionnaires at baseline, 1- and 6-weeks, and 6-months post workshop. Attendees' baseline QOL scores were compared to follow up (FUP) scores. Scores from patients receiving routine FUP care were also compiled as a reference population.

Results: Seventy-seven patients attended one of nine workshops. Mean satisfaction was 9.7/10 with the workshop, and 9.96/10 with the moderator. Participants' baseline mean Patient-Reported Outcomes Measurement Information System (PROMIS) anxiety and depression scores were 57.8 ± 6.9 and 55.3 ± 7.5 , significantly higher than routine FUP care patients (49.1 ± 8.3 and 47.3 ± 8 respectively). PROMIS anxiety and depression scores decreased and Happiness Index Profile (HIP-10), measuring intention and resiliency, increased significantly at 1- and 6-week FUPs.

Conclusions: Pathways for Survivors was favorably received. Anxiety and depression decreased significantly at 1- and 6-weeks post workshop and remained below baseline at 6 months. Increased HIP-10 scores support that patients incorporated skills from the workshop. A one-day workshop led by a lay moderator significantly improved several psychological measures, suggesting it may be a useful and time-efficient strategy to improve QOL in breast cancer survivors. We are investigating whether an abbreviated "booster" of the intervention at a later date could further improve and maintain QOL gains.

1. Background

There were an estimated 3.8 million breast cancer survivors in the US in 2019 and the number is expected to be close to 5 million by 2030. [1] Transitioning from cancer patient to survivor is challenging, and many breast cancer patients have unmet physical and emotional needs. [2–5] Studies have found increased rates of anxiety and depression among breast cancer survivors both short and long term, and these problems appear more prominent in younger survivors and those with pre-existing psychological symptoms. [4, 6, 7] Many studies also identify fear of cancer recurrence (FCR) and difficulty in returning to "normalcy" as potential sources of distress in this population. [4, 8, 9]. The nature of intrusive thoughts associated FCR have been shown to share many characteristics with worry or anxiety [10]. Moreover, a systematic review in adult cancer survivors found that depression and anxiety were significantly correlated with FCR, and psychological distress is a strong predictor of FCR [11]. During the acute phase of care when attending regular medical appointments, patients often feel more secure that there is active monitoring for signs and symptoms of cancer recurrence. After active treatment ends, breast cancer patients may feel a loss of a safety net. A comprehensive review in breast cancer survivors (≥ 1 year from diagnosis) showed compelling evidence of an increased risk of anxiety, depression and suicide, and neurocognitive and sexual dysfunction in breast cancer survivors compared with women with no prior

cancer. [6] These findings point to the need for novel interventions to help manage these psychological symptoms in breast cancer survivors.

The Pathways for Survivors program was developed through a collaboration between the moderator (GH) and clinicians (MM, HR, DH, and LE) at the University of California San Francisco (UCSF). The basic principles and content of the Pathways workshop are based on a positive psychology model of cognitive behavioral therapy (CBT). This model, consistent with the Broaden-and-Build theory of positive psychology, suggests that experiencing positive emotions broadens a person's awareness and encourages varied and novel thoughts and actions, which in turn strengthens the individual's personal skills and resources [12]. Multiple CBT interventions have been shown to decrease anxiety and depression in various breast cancer populations. [13–17]

The Pathways for Survivors program teaches specific techniques for increasing positive emotions on a daily basis, equipping patients with a variety of skills and tools to improve their quality of life in the context of life-limiting illness. The intervention is based on a system of 9 behaviors which have been shown in other contexts to enhance quality of life and emotional wellbeing. [18, 19] With the aid of grant and philanthropic funding, the UCSF Breast Care Center (BCC) has offered Pathways workshops several times a year since 2015 as a free resource to breast cancer survivors, with a focus on patients who recently completed active treatment. Qualitative and quantitative feedback on the acceptability and utility of Pathways for Survivors has been collected on the program for quality improvement purposes, allowing us to better characterize the acceptability and psychological impact of the workshop. We hypothesized that this day-long workshop would have favorable effects on patient quality of life by reducing both short- and long-term anxiety and depression.

2. Materials And Methods

Stage 0–3 breast cancer patients who had at least one clinic visit at the UCSF BCC and had completed their acute phase of care, including chemotherapy and breast surgery, were considered eligible and were invited to attend a day-long Pathways for Survivors workshop. Patients were recruited by their medical oncologist or breast surgeon, through flyers posted in UCSF clinics, and at local breast cancer survivorship and supportive care events. For the last 2 sessions, workshops were limited to patients age 50 and under since the philanthropic funding to support these two workshops was intended to focus on “younger” breast cancer survivors. The workshops were conducted on a weekend day, lasting from approximately 8:30am-4:00pm with a 45-minute lunch break during which patients were encouraged to engage in informal interaction. The workshops were moderated by author GH and included a series of nine lessons or exercises, most of which required substantial interaction between the participants. The central framework of the workshop was centered on “intention” which is defined in this program as “making a conscious choice toward the most beneficial thought, feeling, or behavior”. Other exercises were based on the concepts of truth, accountability, identification, centrality, recasting, options, appreciation, and giving. At the completion of the workshop, participants were asked to complete anonymous feedback surveys on program content and moderator quality.

Attendees were asked to complete a series of electronic surveys via the REDCap system at baseline (before the day-long program), 1-week post-workshop, and 6-weeks post-workshop. For the last four workshops, a 6-month follow up survey was added. Within the questionnaire, patients were presented with a consent to have their data used for research purposes. However, patients could opt to participate in the workshop and opt out of data sharing. Specific survey measures included NCI PROMIS (Patient-Reported Outcomes Measurement Information System) anxiety and depression short-forms, and the Happiness Index Profile (HIP-10) scale, a measure of psychological intention and resiliency.

PROMIS Anxiety and Depression are two independent short-form 4-item questionnaires that assess self-reported anxiety and depression in the past 7 days. Each item is scored from 1 (never) to 5 (always), with higher scores indicating greater anxiety or depression. PROMIS Instruments were graded using item-level calibrations using the Health Measures Scoring Service (https://www.assessmentcenter.net/ac_scoring-service) to determine PROMIS Anxiety and Depression T Scores.

The Happiness Index Profile (HIP-10; previously HI/P6 scale) is a 10-item questionnaire assessing positive affect, intention, and resiliency. Each item is scored from 0 (strongly disagree) to 10 (strongly agree). HIP-10 scores are calculated by adding the scores for each item to generate a total score out of 100, and an increase in the score suggests greater uptake of the “intention” model. Through an independent validation in a population including college students, employees of large corporations, and retirees was HIP-10 was found to have high internal consistency (Cronbach’s Alpha = 0.847) and correlation with the POMS (Profiles of Moods) total scale and multiple subscales. [20]

Within the UCSF BCC, all new patients are asked to complete an intake survey that includes demographic information, health history, and QOL instruments including PROMIS anxiety and depression. We have also implemented electronic delivery of follow-up surveys to early stage patients in ongoing routine care. A subset of these patients agreed to have their survey data used for research. In order to better contextualize the Pathways patients’ baseline scores within a broader general population of early stage follow up patients at the UCSF BCC, we utilized data from patients who had completed a follow up survey, did not attend Pathways, and who consented to have their data used for research. These patients are identified in this manuscript as the “comparison group”.

The primary goal of this study was to evaluate longitudinal change in patient reported psychological distress measures, including PROMIS depression and anxiety, and HIP-10 and to evaluate demographic and clinical covariates within this population that may help predict patients who would benefit most from this intervention.

We also compared baseline PROMIS anxiety and depression scores as well as demographic and clinical descriptors of the Pathways patients to a comparison group of early stage follow up patients along with their PROMIS anxiety and depression scores collected at a single follow up survey.

2.1 Statistical Analysis

Descriptive statistics were used to summarize demographic and clinical data including age, stage, hormone receptor and HER2 status, nodal status, and time from diagnosis to completion of baseline survey for Pathways participants. Independent-samples t-test and chi-square tests were conducted to compare demographics for Pathways participants and the comparison group. Independent two-sample t-tests were also used to compare the one-time scores on the PROMIS anxiety and depression scales of the comparison group to baseline scores of Pathways participants.

For Pathways participants, paired T-tests were used to compare the PROMIS anxiety, depression and HIP-10 scores between baseline and the 1-week, 6-week, and 6-month scores for significance. Two-tailed p values of < 0.05 were considered significant. Among Pathways participants, analyses were conducted using paired t-tests to determine if factors including age, stage, nodal status, hormone receptor status or time from diagnosis were associated with the change from baseline in PROMIS and HIP-10 scores at 1-week, 6-weeks, and 6-months.

3. Results

Nine sessions were held between 9/2015-12/2019. 79 patients participated in the Pathways workshop and provided feedback on their satisfaction with the day-long session. 77 patients consented to have their quality of life data (including PROMIS and HIP-10) used for research. 71 patients completed at least 1 follow up survey. Of those patients, 68 patients completed the 1-week follow-up (completion rate = 88%) and 61 patients completed the 6-week follow-up (completion rate = 80%). The 6-month follow-up survey was sent to participants from the last 4 workshops. Of the 50 patients invited to complete the 6-month survey, 32 completed it (completion rate = 65%).

Demographic data for Pathways participants and the routine follow-up comparison group patients who agreed to use of their clinically collected data for research is presented in Table 1. Pathways participants were younger than the routine follow-up care patients (mean 51.3 vs. 58.5 years, $p < 0.001$). There were no significant differences in stage, hormone receptor status, HER2 status, or nodal status. Pathways participants were, on average, 1.5 years from their diagnosis. The majority of participants were white (75.3%), well-educated (college graduates or above, 92%), and working (45% full time or 22% part-time).

Table 1

Demographic and Clinical Characteristics of Pathways Participants and Early Stage Routine Follow-up Care Patients

Description	Pathways Participants	Routine Care	p-Value
N	77	71	
Age			
. Mean (St Dev)	51.4 (10.74)	58.5 (11.79)	< 0.001
. Median	51.3	59.0	
Stage			0.30
...Stage 0 or 1	31 (40.3%)	23 (32.4%)	
...Stage 2 or 3	46 (59.7%)	48 (67.6%)	
HR Status			0.13
...Negative	13 (16.9%)	6 (8.5%)	
...Positive	64 (83.1%)	65 (91.5%)	
HER2 Status			0.30
...Negative	61 (79.2%)	51 (71.8%)	
...Positive	16 (20.8%)	20 (28.2%)	
Nodal Involvement			0.06
...No	50 (64.9%)	36 (50.7%)	
...Yes	26 (33.8%)	35 (49.3%)	
Treatment Length			
... Less 6 months	22 (28.6%)	N/A	
...Greater than/equal to 6 months	55 (71.4%)	N/A	
Race			
White	58 (75.3%)		
Asian	11 (14.3%)		
Other	6 (8%)		
Not Reported	2 (2.6%)		
Education			

Description	Pathways Participants	Routine Care	p-Value
... Some high school or less	0 (0%)		
... High school graduate/GED degree	1 (1.3%)		
... Some college or technical school	5 (6.5%)		
... College graduate	26 (33.8%)		
... Some graduate school	2 (2.6%)		
... Master's degree	30 (39.0%)		
... PhD, MD, JD, or other	13 (16.9%)		
Employment Status			
... Full-time (35 hours/week or more)	35 (45.5%)		
... Part-time (Less than 35 hours/week)	17 (22.1%)		
... Full-time parenting or caregiving	4 (5.2%)		
... Student	1 (1.3%)		
... Retired	8 (10.4%)		
... On leave/disability	7 (9.1%)		
... Other	5 (6.5%)		
Annual Income			
... Less than \$25,000	8 (10.5%)		
... \$25,000 to \$49,999	4 (5.3%)		
... \$50,000 to \$74,999	10 (13.2%)		
... \$75,000 to \$99,999	11 (14.5%)		
... Over \$100,000	43 (56.6%)		
Health Insurance			
... Health insurance through employer	42 (54.5%)		
... Health insurance through partner's employer	18 (23.4%)		
... Private health insurance	11 (14.3%)		
... Medi-Cal/ Medicare/ Medicaid or some other public coverage	6 (7.8%)		
Marital Status			

Description	Pathways Participants	Routine Care	p-Value
... Married	46 (59.7%)		
... In a committed relationship	11 (14.3%)		
... Single	12 (15.6%)		
... Divorced/separated	8 (10.4 %)		

Pathways participants had significantly higher baseline PROMIS anxiety and depression scores than the scores from a single follow up time point in the routine follow up comparison group. The baseline PROMIS anxiety mean score was 57.8 (SD = 6.9) for Pathways patients, versus 49.1 (SD = 8.3) for the comparison group patients. Similarly, the baseline PROMIS depression mean score was 55.3 (SD = 7.5) for Pathways patients, versus 47.3 (SD = 8) for the comparison group patients ($p < 0.001$ for both comparisons).

The distribution of PROMIS depression and anxiety and HIP-10 scores over time are depicted in Fig. 1. PROMIS anxiety scores decreased significantly at 1-week (Mdiff = 3.884, SD = 6.616; $p < 0.0001$) and 6-weeks (Mdiff = 2.234, SD = 7.291; $p = 0.02$) and showed a non-significant decrease at 6-months follow up (Mdiff = 2.466, SD = 7.613; $p = 0.07$). PROMIS depression scores decreased significantly at 1-week (Mdiff = 4.260, SD = 6.811; $p < 0.0001$) and 6-weeks (Mdiff = 3.175, SD = 6.669; $p < 0.001$) but increased nearly back to baseline at 6-months (Mdiff = 0.822, SD = 6.962; $p = 0.5$). HIP-10 scores increased significantly at 1-week (Mdiff = 6.63, SD = 12.41; $p < 0.0001$) and 6-weeks (Mdiff = 6.21, SD = 13.37; $p < 0.001$) and maintained a trend towards increase out to 6-months (Mdiff = -3.62, SD = 12.811; $p = 0.12$). Table 2 summarizes changes in scores for Pathways participants compared to their baseline.

Table 2
Summary of outcomes in Pathways participants compared to baseline

Item	N	Mean Change	LowerCL Mean	UpperCL Mean	Std-Deviation	Std-Error	T-Value	DF	P-Value
PROMIS Anxiety T Score									
Baseline – 1-week Follow Up	68	3.884	2.282	5.485	6.616	0.802	4.8409	67.00	0.0000
Baseline – 6-week Follow Up	61	2.234	0.367	4.102	7.291	0.934	2.3936	60.00	0.0198
Baseline – 6-month Follow Up	32	2.466	-0.279	5.210	7.613	1.346	1.8321	31.00	0.0766
PROMIS Depression T Score									
Baseline – 1-week Follow Up	68	4.260	2.612	5.909	6.811	0.826	5.1583	67.00	0.0000
Baseline – 6-week Follow Up	61	3.175	1.467	4.883	6.669	0.854	3.7188	60.00	0.0004
Baseline – 6-month Follow Up	32	0.822	-1.688	3.332	6.962	1.231	0.6678	31.00	0.5092
HIP-10									
Baseline – 1-week Follow Up	68	-6.632	-9.636	-3.629	12.410	1.505	-4.4072	67.00	0.0000

Item	N	Mean Change	LowerCL Mean	UpperCL Mean	Std-Deviation	Std-Error	T-Value	DF	P-Value
Baseline – 6-week Follow Up	61	-6.213	-9.639	-2.787	13.375	1.713	-3.6280	60.00	0.0006
Baseline – 6-month Follow Up	32	-3.625	-8.244	0.994	12.811	2.265	-1.6007	31.00	0.1196

There were no statistically significant differences in changes in PROMIS anxiety, PROMIS depression, or HIP-10 scores of participants based on time from completion of active treatment to the time of workshop (≤ 6 months vs. >6 months), stage (stage 0 or 1 vs. stage 2 or 3), hormone receptor status (positive vs. negative) or nodal status at any follow up point. Participants with HER2 positive disease had a greater decrease in PROMIS depression scores compared to HER2 negative participants at all follow-ups, although the difference was only significant at the 6-week follow-up ($p = 0.02$). Comparing HER2 positive vs. negative participants, there were no statistically significant differences in changes in PROMIS anxiety or HIP-10 scores from baseline to any follow up. Participants who had a shorter treatment duration (≤ 6 months) had a greater decrease in PROMIS anxiety scores compared to participants with longer treatment duration (> 6 months) at all follow-ups, although the difference was only significant at the 6-week follow-up ($p = 0.049$). There were no statistical differences in PROMIS depression or HIP-10 scores at any follow up based on treatment length.

The average scores for satisfaction with the workshop and the moderator were 9.70 and 9.96 respectively. 98.5% would recommend the workshop to other survivors. In the immediate feedback provided at the end of the workshop, comments were all favorable and included statements such as: “This program truly gives me a pathway and an orientation of self-care. Instead of being stuck in fear, I have now a way towards a full life” and “The program offers an opportunity for “pause” in a time of great stress caused by dealing with disease and how it upends life...The skills/tools are useful in all aspects of life”.

In responding to the question of what were the most helpful parts of the program, comments included “The constant participation of everyone in the group. It was great to learn from others' experiences. The intentions and appreciations parts were my favorites” and, “I most enjoyed the recasting, as it provided an intimate listening and sharing setting. I also enjoyed the appreciation line – although it was difficult, it was amazing to see connections had formed in a short space of time”.

Some comments regarding areas for improvement were “Would be willing to do two days and/or reconnecting or having a checking in in 3 months/6 months”, “A longer program so as to allow the

participants more time to share”, and “Perhaps it could be done in two shorter sessions (3–4 hours each) to give the participants time to reflect on the first session before doing the second– it’s a lot to take in!”

4. Discussion

The Pathways for Survivors workshop was well received by patients and the overwhelming majority would recommend the workshop to other cancer survivors. Participants’ PROMIS anxiety and depression scores decreased significantly up to 6 weeks post workshop. Improvements in these quality of life measures did not appear to differ based on stage, time from end of active treatment, nodal status, or hormone status. Increased HIP-10 scores at 1-week and 6-week follow ups suggested that patients incorporated the intention and resiliency skills that were the focus of the workshop. While the 6-month follow-ups for anxiety and HIP-10 showed a trend towards improvement compared to baseline, these results were not statistically significant. This may be due to the smaller sample size, given that the 6 month follow up survey was only distributed to participants in the last 4 workshops and a lower percentage (65%) of participants completed the 6 month follow up as compared to the 1 and 6 week follow ups (88 and 80%, respectively). It is also possible that the skills learned in the workshops may need to be reinforced with additional “booster” sessions. A randomized clinical trial of 8 weeks of cognitive behavioral therapy followed by 3 booster sessions in metastatic breast cancer patients found sustained reductions in depressive symptoms and anxiety out to 6 months, supporting this hypothesis. [21]

Patients who participated in the Pathways workshops, on average, had more anxiety and depression at baseline than a reference population of early stage patients receiving routine follow-up care at the UCSF BCC. Pathways participants were younger, closer to their diagnosis of breast cancer, and had more recently entered the “survivorship” phase of care than the reference group of routine follow up care patients. Notably, many of the Pathways patients were recruited by their medical or surgical oncologist to attend the Pathways workshop, and the providers likely identified patients who they thought had more psychological distress and would benefit from the intervention. Finally, the last 2 workshops were specifically targeted at younger women (< 50 years of age), where the additional stresses of having children or returning to the workforce after a cancer diagnosis may be associated with greater anxiety and/or depression. [22, 23]

While it is possible that the improvements seen in the Pathways participants over time represents a natural trend of emotional and psychological recovery from the diagnosis of breast cancer and its treatment, the significant drop in PROMIS anxiety and depression scores and improvement in the HIP-10 scores immediately post workshop as early as the 1-week time point and sustained until 6-weeks suggests an immediate impact from the workshop. Although the intervention effect size seems to diminish at the 6-month follow up, there are still trends toward lessened anxiety and depression, and improvements in the HIP-10, a measure of self-efficacy and tendency towards making positive and intentional behavior choices.

The Pathways for Survivors workshop was based on an “intention model” which has been applied within numerous business and human resource settings and has been pragmatically refined over time. A pilot study among cardiac rehabilitation patients and their caregivers, also incorporating this “intention model”, resulted in more positive attitudes and an improved sense of control and hope related to health, which remained stable at follow-up out to 12 weeks.

[24] Multiple other positive psychology interventions including mindfulness, expressive writing, and creation of hope have been studied and found to have an overall favorable impact on the quality of life of breast cancer patients. [25]

Although a formal mixed methods analysis to evaluate common themes of the feedback was not conducted, participants’ comments reflected that they valued the toolkit of “setting intentions”, exploring obstacles, and incorporation of exercises in gratitude and recasting. Participants also rated the group experience as an important aspect of the workshop and reported that the opportunity to interact with other survivors, share experiences, and actively engage in discussions helped bring the concepts to life. Although this was a skills-based workshop, prior research has shown that breast cancer support groups and other forms of peer support provide emotional and informational benefits, although their short- and long-term impact on anxiety and depression is not fully proven. [26, 27]

Previous studies have supported the efficacy of cognitive-behavioral and mindfulness-based therapies in cancer patients in addressing fear of cancer recurrence, depression, anxiety, and quality of life. A meta-analysis of cognitive behavioral interventions in breast cancer patients undergoing active treatment found that these techniques had a significant effect in reducing anxiety and depression, and reported that while therapy length or delivery did not significantly moderate the effect, individual therapy showed a slight trend towards eliciting better results on distress outcomes. [13] Another meta-analysis review of mindfulness-based stress reduction programs by Zhang et al. reported that most programs were 6–8 weeks long, and had statistically significant effects on anxiety and depression. [17] A randomized controlled trial looking at breast, prostate and colorectal cancer survivors receiving 8 sessions of blended cognitive behavior therapy found a significant decrease in fear of cancer recurrence as well as anxiety and depression on the Hospital Anxiety and Depression scale at 3 months from baseline [16]. A pilot study of a one to two day psychosocial intervention combining mindfulness based cognitive behavioral therapy and covering anxiety management and relationships/sexuality issues for young breast cancer survivors was well received and resulted in an overall gain in self-reported knowledge and confidence among participants [28]. This pilot study led to a much larger randomized controlled trial of a mindfulness-based program compared to survivorship education and a waitlist control for management of depressive symptoms in younger breast cancer survivors. Our intervention is unique from many previously reported in that it involves only a single session and is led by a lay moderator, making it more convenient and accessible to a population of patients who may find it challenging to attend multiple weekly sessions.

4.1 Study Limitations

Though the results support an improvement in anxiety, depression, and intention and resiliency as immediately as 1 week post workshop suggesting a direct impact of the intervention, as with many previously reported interventional studies attempting to impact quality of life in the survivorship population, this was not a randomized trial. Nonetheless we attempted to contextualize the Pathways participants, both in terms of clinical and demographic factors, and baseline anxiety and depression scores in comparison to a reference sub-population of general early-stage breast cancer follow-up patients. However, our routine care population was only sampled at one time-point and therefore we do not have a trajectory of their PROMIS anxiety and depression scores over time and, thus, does not serve as a true control group. Pathways participants were generally younger than both the average breast cancer survivor as well as our comparison group, and were of a high socioeconomic status (graduate degree holders, >\$100,000 annual income) and working full time. As an academic center, we attract a higher risk and younger patient population and have focused on developing supportive care programs for these patients, thus skewing our population sample. Further research with more heterogeneous patients and with a larger 6 month follow-up sample is needed to confirm that the positive impact on several quality of life measures from this positive psychology/mindfulness and skills based workshop can be sustained and also observed in a more diverse population

4.2 Clinical Implications and Conclusions

Our study supports the Pathways for Survivors workshop as a highly satisfying and time-efficient means for breast cancer survivors to learn behavioral skills that may improve emotional well-being and potentially overall quality of life. Future research is necessary to explore the impact of alternate moderators and integration of video conferencing, to understand the value of additional “booster” sessions to reinforce the skills and concepts illustrated in the present workshop, and to evaluate longer-term impact.

Declarations

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Conflict of Interest: The authors declare that they have no conflict of interest

Availability of data and material: The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions: MMe, GH, JH, DH and EW conceived and designed the study and analysis. SU, MEM, MMe, MMa, DH, EH and EW collected the data. SU, MMa, JH and MMe performed the analysis. SU, MEM, MMe wrote the manuscript with the help of GH, EW, JC, HR and LE.

Code Availability: N/A

Ethics Approval:

Approval was obtained from the ethics committee of University of California, San Francisco (Study Number 15-17099). The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

Consent to participate:

Informed consent was obtained from all individual participants included in the study.

Consent for publication:

Patients signed informed consent regarding publishing their de-identified data.

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Figures

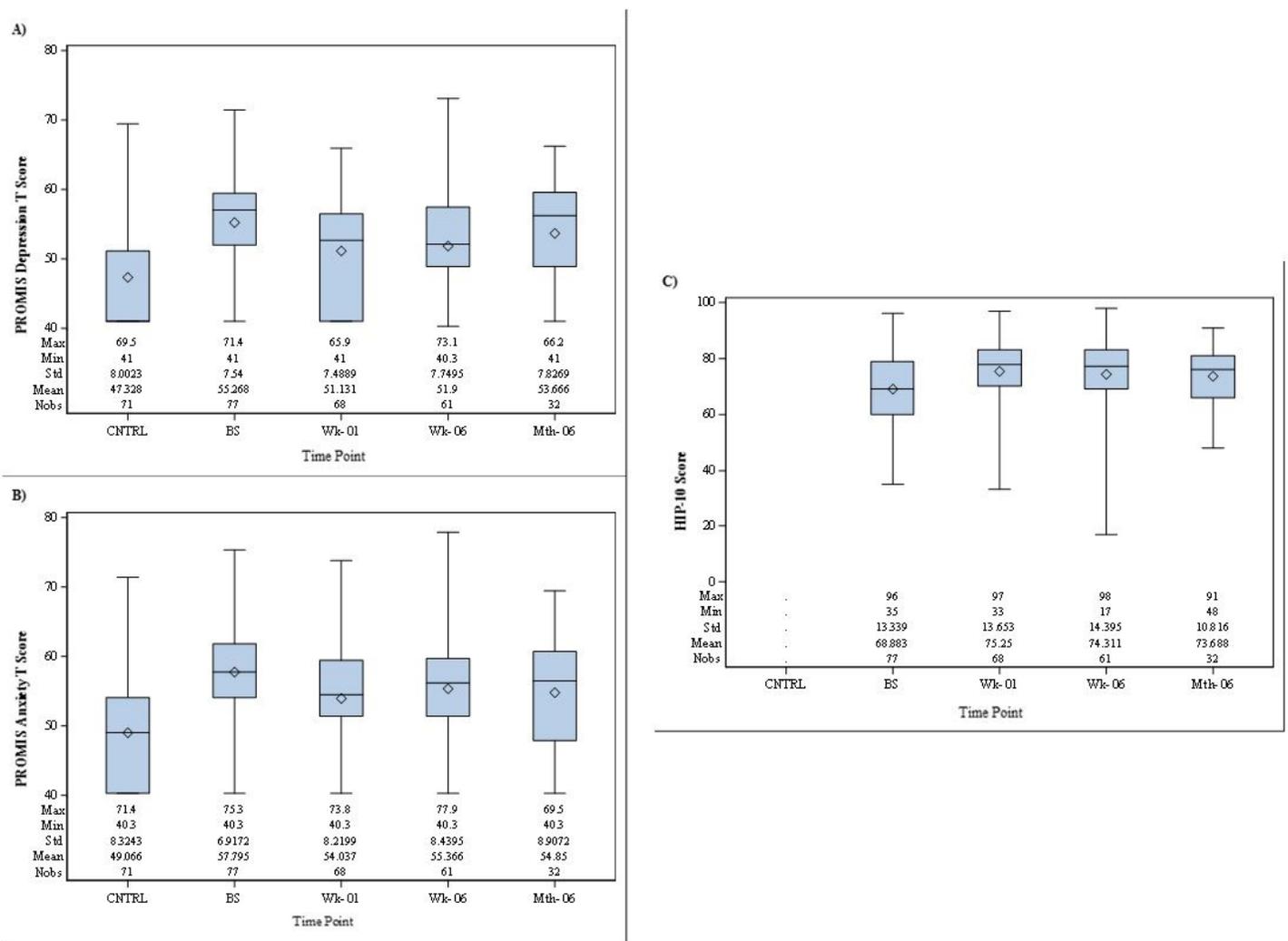


Figure 1

Distribution of (A) PROMIS Depression T Scores, (B) PROMIS Anxiety T Scores, and, (C) HIP-10 scores at baseline (participants and comparison group) and follow up (participants only) * CNTRL = baseline comparison group; Nobs = number of observations; BS = baseline