BRIEF DEPRESSION LITERACY INTERVENTION WITH PALLIATIVE CANCER OUTPATIENTS

by

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ABSTRACT

Cancer patients are at risk for depression due to the nature of their disease. Previous investigations indicate patients meeting screening criteria for depression may be underdiagnosed or undertreated for their symptoms. For cancer patients, psychological distress may exacerbate pain, increase desire for hastened death, and increase disability.

A randomized controlled trial (RCT) design was employed to determine feasibility and efficacy of a one-time, in-person psychoeducation and depression literacy intervention by comparing it to a treatment as usual (TAU) control group. Outpatient palliative care patients were eligible with PHQ-9 score ≥5, cancer diagnosis, absence of SMI or cognitive impairment, 19 years or older, able to speak and understand English, and available to be reached and communicate by telephone. Baseline and one month follow-up telephone assessments used vignettes and questionnaires to assess depression literacy, psychological distress, and disability. Forty-three patients enrolled, majority white (65%) females (75%) with mean age of 48 years (SD= 11.08). Three intervention participants dropped out before completing the intervention visit and follow-up interview; therefore, 40 participants were included in analysis. Group differences were controlled using propensity score. Intervention participants demonstrated clinically relevant change in depression literacy including: symptom identification (OR=2.0, 95%CI=0.296-13.511), likelihood to seek MH care with counselors (OR=4.059, 95%CI=0.388-42.491), psychiatrists (OR=4.2, 95%CI=0.397-44.4), and social workers (OR=4.2, 95%CI=0.397-44.401), and improved perceptions toward employees (OR=2.556, 95%CI=0.214-30.469) and parents (OR=15.333, 95%CI=1.711-137.404) with severe depression. Decreased somatic complaints

(M=-1.7, SE=1.68, d=-0.378) and more stable level of disability were also found (M=-3.0, SE=3.36, d=-0.319).

Although results are promising, future studies with more participants, improved outcome measurement, and diversity in the sample are warranted to improve the understanding of the magnitude of change in depression literacy between groups, and improve the generalizability of findings. Integration of the intervention across time, within the clinical setting may increase uptake and completion of the intervention. Also, long term follow-up would allow researchers to track the effect of the intervention on help-seeking behaviors.

DEDICATION

To Lucas: May you too see the bounty from the fruits of your labor and perseverance.

LIST OF ABBREVIATIONS AND SYMBOLS

MH	Mental health
TAU	Treatment as usual
US	United States
PHQ-9	Patient Health Questionnaire
=	Equal to
≥	Greater than or equal to
MDASI	MD Anderson Symptom Burden Inventory
SPMSQ	Short Portable Mental Status Questionnaire
IDLS	International Depression Literacy Survey
K10	Kessler Psychological Distress Scale
SPHERE	Somatic and Psychological HEalth Report
IMPACT	Improving Mood- Promoting Access to Collaborative Treatment
d	Cohen's d
SD	Standard deviation
INT	Intervention group
p	Probability associated with the occurrence under the null hypothesis of a value as extreme as or more extreme than the observed value
N	Total Number of cases
n	Number of cases (generally in a subsample)
appt	appointment
>	Greater than
OR	Odds ratio

CI	Confidence interval
M	Mean the sum of a set of measurements divided by the number of measurements in the set
SE	Standard error (the standard deviation of the sampling distribution of a statistic)

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CHAPTER 1

INTRODUCTION

In 2004, almost half of all Americans, or 133 million people, were living with a chronic condition and projections anticipate 1% increase each year until 2030.[1] Eighty-one percent of people with serious chronic conditions see two or more different physicians annually.[2] Depressive and other psychological disorders assume an important role in the etiology, course, and outcomes associated with chronic disease.[3] The current prevalence estimate is that about 25% of the US population is affected by mental disorders during a given year.[4] Increased recognition of the high comorbidity of depression and chronic conditions,[5] has led to the development of integrated mental health (MH) programs that incorporate MH screening[6] and services into care settings treating chronically ill patients. Collaborative care[7] is an approach in which physicians and MH providers collaborate in an organized way to manage common mental disorders. Such programs are pragmatic and apply principles of chronic disease management, including establishing and sustaining effective communication and collaboration between primary care, MH providers, and care managers. This collaboration may support systematic diagnosis, outcomes tracking, and facilitate adjustment of treatments based on clinical outcomes (stepped care).[8,9] Although collaborative care models are designed to increase the likelihood that patients are identified and receive adequate treatment for MH it is still widely understood that many patients go untreated.

Palliative and Supportive Care

As defined by the National Consensus Project for Quality Palliative Care[10], palliative care is a structured system of delivering care to individuals with life-threatening or debilitating illness. Its focus is on effective management of pain and other distressing symptoms, while incorporating psychosocial and spiritual care according to patient/family needs, values, beliefs and cultures. Therefore, by definition, palliative care should employ a multidisciplinary approach to treatment in order to meet all aspects of patient's needs. According to the definition provided by the Milbank's Report[11], the study recruitment site is based within a basic collaboration on-site care model because psychologists and palliative care physicians have separate systems, but share the same facility. As the report suggests, sharing the same physical space allows for more communication, but each provider remains in their own professional culture.

As a new medical profession, palliative care is often misunderstood and therefore underutilized by referring physicians and the general population.[12] These misunderstandings are sometimes perpetuated by cultural stigma surrounding death and dying. Similarly, general MH service utilization suffers from misinformation, lack of information, and cultural stigma, which can in turn lead to underutilization. Palliative care and MH also share similar populations, in that younger, white women tend to use palliative medicine and MH services more frequently than other groups.[12,13] In spite of the NCP guidelines specifying the psychosocial role of palliative care, up-take of MH care remains problematic. Many psychological disorders, especially depression,[14,15] have been unrecognized or under-treated within palliative care settings.[16]

Outpatient treatment providers in the recruitment site have been tracking clinical outcomes for over five years with the goals of improving treatment quality and disseminating information about outpatient palliative care through research. In 2009, 84% of the clinic had a

cancer diagnosis, often receiving concurrent oncological treatment, and presenting for care related to symptom management (e.g., pain, fatigue, etc), psychological treatment, and goals of care determination (e.g., clarifying goals and priorities with the physician as they move across the trajectory from curative, palliative, and terminal). The remaining outpatients have advanced life-threatening diseases, such as late-stage lung, heart, or neurological illness.[17] Azuero and colleagues[17] determined when access (financial and provider access) was controlled for, utilization of psychological services for palliative outpatients with depression symptoms was only 50%. They found the more often the patient visited the clinic and the more providers patients were evaluated by, the more likely they were to seek on-site MH services. This was hypothesized to be related to exposure (giving physicians more opportunity to diagnose and treat mood disturbance) and severity of patient's illness.[17]

Cancer

Referrals to palliative care among cancer patients are most often related to their complex disease trajectory and the need for supportive treatment across the disease spectrum. The need for supportive treatment is credited to the fact that, in addition to physical suffering, psychological comorbidities are increasingly recognized as major components of distress.[18] Several factors contribute to psychological distress in individuals with cancer[19], including the grief about current and anticipated losses, fear of death, concerns about loved ones, the effect of certain chemotherapeutic drugs on mood[20-23], and the biology of the malignancy.[24]

Kadan-Lottick et al.[18] found that 12% of terminal cancer patients met criteria for a major psychiatric condition, a statistic similar to the general population.[25] According to self-report, 28% accessed a MH intervention for a psychiatric illness since the cancer diagnosis, 17% had discussions with a MH professional and 90% were willing to receive treatment for emotional

problems. Cancer patients that discussed psychological concerns with MH staff and white patients were more likely to receive MH services.[18]

Although psychiatric disorders in cancer patients are highly treatable,[26,27] studies suggest healthcare providers do not adequately address mental illness in this population.[28-31] Ford and colleagues[29] audio-taped patient-doctor outpatient clinic encounters for 117 patients who received "bad news" about a cancer diagnosis at a tertiary care center. Although patients spent 14% of the time talking about their psychosocial concerns, clinicians only devoted 3% of their verbalizations to addressing them. In a large study of 1,109 cancer patients, oncologists were concordant with patient-completed scales of depression in only 13% of patients reporting the severe range of symptoms.[30] In the same study sample, nurses tended to under recognize severe depressive symptoms at similar rates.[31]

Untreated psychological distress in cancer patients is associated with amplified pain,[30] increased desire for hastened death,[32] increased disability,[33] impaired ability to participate in end-of-life planning,[19] and diminished psychosocial functioning of caregivers.[34]

Mental Health Literacy

MH literacy is defined as "knowledge and beliefs about mental disorders which aid their recognition, management or prevention".[35] Jorm and colleagues[35] define MH literacy as comprising 6 constructs: (a) ability to recognize specific disorders or different types of psychological distress; (b) knowledge and beliefs about risk factors and causes; (c) knowledge and beliefs about self-help interventions; (d) knowledge and beliefs about professional help; (e) attitudes which facilitate recognition and appropriate help-seeking; and (f) knowledge of how to seek mental health information.

Cancer patients are all too often uninformed of the psychological toll their illness can take, not only at the time of diagnosis and treatment, but into survivorship as well.[36] Research has demonstrated that individuals are more likely to discuss their emotional concerns with their physician when they can adequately identify their symptoms.[18]

Even when patients and physicians discuss MH care, there are individual differences that may precipitate uptake of the practitioner's recommendations. For instance, Jorm and colleagues[37] found that people who believe that antidepressants are harmful are more negative about other standard treatments including psychological ones, indicating that for some people there is a rejection of treatment in general. Also, in a survey in six European countries, around one third of adults endorsed beliefs that professional MH care is worse than or equal to no help at all for mental disorders.[38] These investigators found, however, that the perceived effectiveness of MH care was associated with actually receiving MH care.[38] In relation to beliefs about medication, depressed patients who have negative attitudes toward antidepressants are less likely to be prescribed these medications, less likely to fill prescriptions, and less likely to benefit overall.[39] Therefore, if people diagnosed with mental disorders are to receive the full benefits of evidence-based health care, patient perception of treatment should be assessed by their provider and education provided with the goal of developing a collaborative care plan.[40]

Research has demonstrated that by increasing MH literacy alone, some therapeutic benefit may be achieved.[41] One psychoeducation information website reduced depressive symptoms more than attention-placebo control and produced effects equivalent to those of the cognitive-behavior therapy website. These therapeutic benefits were found to be maintained over 12 months.[42]

Specific Aims

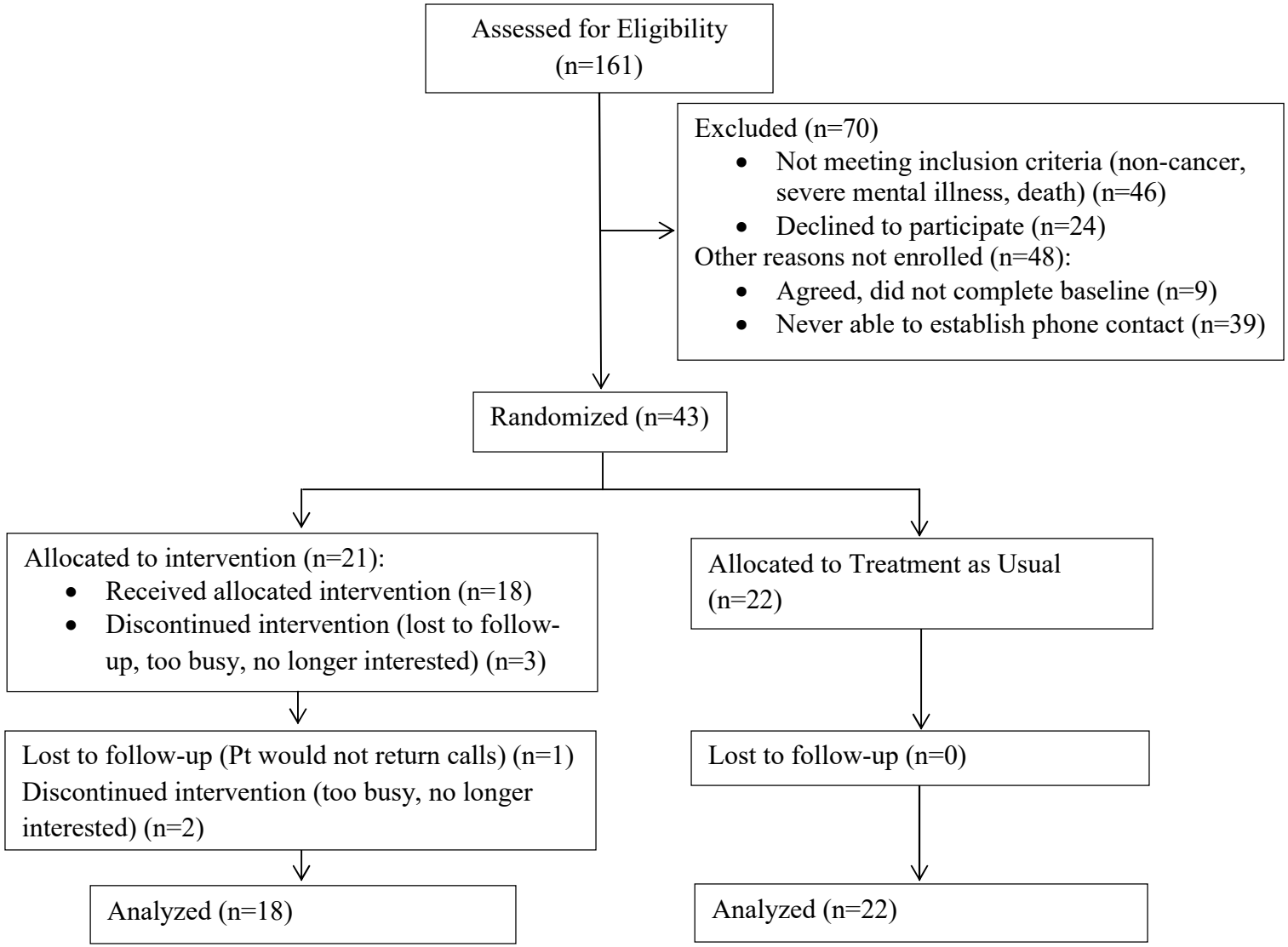
The investigators' aims of the current study were: (a) to determine feasibility of a brief depression literacy psychoeducation intervention with depressed palliative outpatients with cancer; and (b) to evaluate the efficacy of the one-time intervention in comparison to a treatment as usual (TAU) control group in improving patients' depression literacy. A secondary aim was to assess and compare change in psychological distress and disability in the intervention group compared to the TAU group.

CHAPTER 2

METHOD

All participants were recruited from an outpatient palliative care clinic at a university medical center in the southeastern region of the US. Two institutional review boards approved the study protocol. Researchers utilized the clinical surveillance protocol employed in the clinical setting, which assesses outcomes from each patient at every clinic visit as a screening tool assessing depression in participants. Figure 1 is a consort diagram that outlines study enrollment. Overall, 161 patients were screened from August 2014 to June 2015. Forty-three patients were randomized with 21 allocated to the intervention group and 22 to the comparison, TAU group.

Figure 1: Consort Diagram



Measures

Demographic

Patient characteristics available in medical records were abstracted at the time of initial review and included: name, date of birth/age, diagnoses (to determine if they have a diagnosis of cancer, depression, anxiety, severe mental illness, and cognitive impairment), type of cancer, and palliative care psychology service treatment history. Other self-report demographic characteristics collected during baseline include: race, gender, education level, marital status, rural or urban dwelling, employment status, and with whom they live.

Screening

The Patient Health Questionnaire (PHQ-9)[43] is a nine item depression scale that is used to assess patient's depression symptomatology, and was administered upon arrival at each palliative outpatient clinic visit. The PHQ-9 was used as the study's screening tool for determining eligible patients. Patients with a score ≥ 5 were deemed to have eligible depression status. The PHQ-9 ranges on a scale from 0-27 with higher scores indicating more severe depression. Scores of 5, 10, 15, and 20 represent cut-points for mild, moderate, moderately severe, and severe depression, respectively.

The MD Anderson Symptom Burden Inventory (MDASI)[44] is also collected as part of the routine patient assessment battery in the outpatient palliative care clinic to assess experienced symptoms in cancer patients. It consists of 10 core symptom items and we focused specifically on the patients' reported level of "sad" symptoms on the sadness scale. Possible scores range from 0-10 with higher scores indicating greater symptom severity.

Short Portable Mental Status Questionnaire (SPMSQ) was used as a screening tool to assess the cognitive status of potential study participants.[45] The assessment was administered

over the telephone with patients that were deemed eligible and expressed interest in participation. Standard SPMSQ cut-scores were used; therefore, patients with no more than 2 errors were considered cognitively intact and eligible to participate.

Outcomes

Mental Health Literacy

Mental health literacy has been measured in many ways in the scientific literature, as there is no gold standard assessment that captures this information. We focused on assessing the constructs of MH literacy described by Jorm et al.[35] with vignettes and a survey. Two different depression vignettes[46-48] (Appendix 1) were used at baseline and follow-up, with the order randomly assigned, in order to control for difficulty level across time points. Vignettes were intended to assess the participant's ability to accurately identify depressive symptoms. There were also 2 "distracter" vignettes paired with each one of the depression vignettes, which depicted symptoms of obsessive compulsive disorder. For each vignette, the participant was asked to imagine the story was about them. Afterwards they were asked, "Would this be a problem for you?" Yes/No, followed by, "If you had to put a name on this, what would you call it?". For the depression vignette, all answers that included 'depression', 'depressed', and 'depressive' were coded as high depression literacy, and all other answers were coded as low depression literacy.

The International Depression Literacy Survey (IDLS)[49] (Appendix 2) contains multiple choice items. This survey does not contain scales and was not developed to assess change across time; therefore, the original survey was modified to include 4 scales: Depression Symptom Identification, Help Seeking from Professionals, Self-Help Seeking, and Attitudes. The sections coincide with Jorm's definition of MH literacy which is described below. The specific scoring

for each is also explained. IDLS questions were all hypothetical and general in nature without focusing on the individual participant's specific MH status.

Ability to recognize depression or different types of psychological distress. This was assessed using the vignettes and IDLS. On the IDLS, respondents nominate (yes/no) whether symptoms listed were symptoms of depression. The list included symptoms of depression and distracter symptoms (symptoms of other mental illness). These depression items were summed (0-19) to give the participant a "Depression Identification Score".

Knowledge and beliefs about risk factors and causes. Patients were asked to identify the prevalence of depression from a multiple choice list. This item was dichotomized as correct/incorrect.

Knowledge and beliefs about professional help and self-help interventions. Respondents were asked their opinion of the *most likely* outcome of depression when treated **and** if not treated with professional help. They were also asked to rate the likelihood they would seek help from professionals or others (self-help), if they were experiencing depression. Their responses were dichotomized (improve/not improve, likely/unlikely respectively) due to lack of variability in endorsed responses.

Items related to seeking professional help were then scored and ranged from 0-6. Similarly, items related to self-help seeking were also scored and ranged from 0-7. Scale scores and individual items were assessed during data analysis.

Knowledge of how to seek MH information. Participants were asked if they have ever looked for information about depression (yes/no) in order to identify experience in seeking information for depression. [49]

Attitudes which facilitate recognition and appropriate help-seeking. Individuals were asked how likely people with depression would be to experience discrimination from a list of potential discriminators. They were also asked to rate how much they agree with statements about people with "*severe depression*" in order to assess stigma. All response options were dichotomized (Likely/Unlikely and Agree/Disagree respectively) and keyed in the same direction (higher scores equal negative attitude). Following, they were combined to create an "Attitude" scale by adding the two together with possible score range from 0-18. Each item was also assessed individually in the dichotomized form.

Psychological Distress

The Kessler Psychological Distress Scale (K10)[50] was included to measure the participant's current levels of psychological distress. Participants were asked how often they experienced each item in the past month. There are 10 items on a 4-point scale with greater score (0-40) indicating greater distress. The 12-item Somatic and Psychological HEalth REport (SPHERE)[51] is used to assess the severity of psychological and somatic symptoms. There are 6 4-point items on each scale (0-18) with higher scores indicating greater frequency of the experienced symptom. The SPHERE asked the participants to report how often they experienced the listed symptoms "in the past few weeks".

Disability

Two disability questions[52] were included and ask the participant to report the total number of days in the past 30 they were, "Unable to complete your usual activities" and "How many days in the past 30 did you spend all or most of the day in bed?". Each item was assessed on the 0-30 range scale individually.

Intervention

In order to ensure continuity and integrity of the intervention, all of the one-time, in-person, intervention visits were delivered by the same master-level clinical psychology graduate assistant and utilized a manual adapted from the patient brochure created for patient education in the IMPACT study.[53] IMPACT is a primary care-based intervention focused on creating a fully integrated interdisciplinary care team in order to treat physical and psychological illness with geriatric patients. Their website contains the education materials they use to educate patients in their intervention (http://impact-uw.org/tools/patient_edu.html). The IMPACT brochure targets a geriatric population with clinic-specific depression treatment modalities, as well as general information about depression and treatment options.

The intervention visits lasted about one hour and were all conducted in-person, either in the clinic or another location preferred by the participant (e.g., their home or work), in an attempt to decrease participant burden. Intervention visits were scheduled directly following the completion of the baseline telephone interview, and were completed within 30 days of their telephone baseline assessment.

The intervention manual was an adapted version of the IMPACT Patient Brochure, tailored for the study design and to correspond with MH literacy constructs. The descriptions below are the intervention components as they correspond with MH literacy constructs:

Ability to <u>recognize</u> specific disorders or different types of psychological distress. Diagnostic criteria and depression symptoms were discussed with the participants. They were encouraged to check the boxes for their experienced symptoms. They were also educated about some commonly endorsed clinical symptoms that are not depression (i.e., alcohol and substance abuse).

Knowledge and beliefs about risk factors and causes. Cancer specific information as it relates to depression (i.e., risk factors, prevalence, reasons for under-diagnosis and under-treatment, and rationale for treatment) was added. Participants were also educated about their individual PHQ-9 score and encouraged to use this information to help guide depression treatment with their palliative care team.

Knowledge and beliefs about self-help interventions. One component of the intervention was focused on behavioral activation. Participants were guided through an exercise that included making a list of pleasant activities they wanted to incorporate in their daily life, eliminating barriers, and effective goal setting. There was an appendix included in the manual with a list of pleasant activities for their reference as well. Participants were also engaged in a discussion on the importance of social support, with focus on ways to activate their support networks and educate their loved ones about their depression. The manual included an appendix with recommendations for how to talk to others about depression.

Knowledge and beliefs about professional help. Patients were educated about pharmacotherapy and psychotherapy options for depression. Brief education was provided on possible side effects of medications and expectations of psychotherapy. The manual also included an appendix with frequently asked questions regarding these two treatment options.

Knowledge of how to seek mental health information. Information was provided for services offered in the interdisciplinary outpatient palliative care clinic as well as in the general community.

Attitudes which facilitate recognition and appropriate help-seeking. Individual patient perspectives about depression were assessed at the beginning of the intervention by the interventionist saying, “Before we open our books and begin, I was hoping you could tell me a

little bit about what depression means to you?" The participant's responses were validated and addressed in relevant sections throughout the intervention visit.

Participants were provided with the print materials for their reference during the intervention. They were also encouraged to follow along and actively participate in activities and discussion during the intervention visit. They were given the manual to take home, and encouraged to use it as a future reference.

The information provided in the manual simultaneously addressed the constructs of MH literacy and their individual needs. In order to ensure integrity of this resource, the intervention was piloted with non-cancer palliative patients from the same clinic to ensure clarity and acceptance of the material. Palliative care patients were identified in a similar manner to the study participants, using PHQ-9 score and diagnosis. Their physicians were also queried as to the appropriateness of the patient for inclusion in the pilot. Specifically, ideal pilot participants were those with a history of being open to expressing their opinion in order to improve their healthcare. Patients deemed appropriate by their physician, were contacted and informed of the purpose of the project. If the patient agreed to participate, the intervention was scheduled. Following the implementation of the intervention, a script with a combination of specific and open-ended questions was used to ascertain the participant's experience with the intervention and the materials used. Three pilot interventions were completed and the intervention materials were determined to meet the criteria necessary to use in the study based on the repetitive positive feedback gleaned from pilot participants. No negative or corrective feedback was ascertained, which is likely due to the fact that the materials were based on an established clinical tool with modifications to address the needs of the target population.

Procedure

Study Visits

Screening, baseline, and intervention visits were conducted by a master-level clinical psychology graduate assistant. The follow-up assessments and all data entry were completed by undergraduate and graduate research assistants, blinded to the participant's group assignment, in order to decrease interviewer bias and likelihood of social desirability bias from participants. Baseline and follow-up visits were completed with the participant over the telephone. For ease of administration for participants answering questions over the telephone, when feasible the response options were consistent and repeated as often as necessary for the participant. Approximately four weeks following the baseline completion date, blinded interviewers called participants to schedule their follow-up visit. All entered data was cross-checked by another research assistant and a final review was completed by the master-level graduate assistant of all entered data.

Randomization

Intervention assignments were randomly predetermined by placing an equal number of each assignment in fifty envelopes, mixing the envelopes up, and then assigning a study identification number to the envelope. Study identification numbers were assigned to the participant in numerical order of enrollment. The envelope with the number corresponding to the participant's study identification number was opened at the completion of the baseline visit.

Data Analysis

Quantitative analyses were conducted using SPSS Version 22. We used abstracted data from medical records to assess descriptive information for patients that enrolled in the study

compared to those that did not. For those that enrolled, descriptive analyses of abstracted and assessed data were used to examine participant's characteristics at baseline.

Continuous study outcome differences for between-group change from baseline to follow-up were assessed using Cohen's d effect sizes of change. Cohen's d was calculated using the pooled standard deviation from baseline. A general threshold for relevance of an observed effect size was selected at d=0.35, which is the mid-point between small (d=0.2) and medium (d=0.5) d-effect sizes as defined by Cohen.[54] This was determined in attempt to detect the smallest effect likely to have clinically relevant implications.

Categorical items that were not dichotomous were dichotomized to facilitate interpretation at the expense of potential loss of power. As described above, scale scores were created to assess symptom identification, professional help seeking, self-help seeking, and attitude, and assessed as continuous variables. They were also examined individually as categorical variables for within-person change resulting in three possibilities: worsening, no change, or improvement. These results were then dichotomized as improved versus no change/worsening. All categorical variable group comparisons were conducted by estimating and testing with logistic regression odds ratios of improvement. The Agresti-Coull method[55] was used for estimating odds ratio with 0 change cells. This method involved creating four pseudo observations with 2 assigned TAU and 2 pseudo observations assigned intervention Following, equal assignment of the response options (0/1) were given to each of the pseudo observations. This method allows for the variable to have to be analyzable by giving each cell observations, without affecting the results. For interpretation, odds ratios were converted to Cramer's V as described by Chinn.[56]

Balance in characteristics of participants between randomized groups were assessed using effect sizes rather than hypothesis testing and p-values, because significance is dependent on sample size. The effect size provides an estimate of the magnitude of a relationship regardless of the sample size. As illustrated in Table 1, the data suggested between-group differences in: living arrangements, employment status, marital status, age, and study completion. Therefore, covariate adjusted analyses via propensity score adjustment were conducted. The propensity score is the probability of assignment to the intervention group given these variables. [57]

Similarly to the assessment of differences in characteristics between randomized groups, effect sizes were used for interpretation of outcome analyses. As explained above, this is due to the relation between sample size and significance.

CHAPTER 3

RESULTS

Table 1 summarizes the background characteristics of the participants. The mean age was 48.2 years (*SD* = 11.08). Seventy-five percent were female and 65% were white. Participants were predominantly educated beyond high school, married, living with only their partner, in urban areas, disabled, with a diagnosis of breast cancer. The majority (64%) did not have past or future appointments scheduled with the outpatient clinic's psychological service. Forty-two percent had a charted diagnosis of depression and 30% had a charted diagnosis of anxiety in their medical record. The mean PHQ-9 score was 13.9 (moderate depression) and MDASI sad symptom item score of 5.9/10. They reported 13 mean days in a month not being able to complete usual activities and 8 mean days spent mostly in bed.

Table 1: Participant Characteristics					
	All participants	INT	TAU	Between-group	
	N=43 (100%)	*n=21 (49%)*	*n=22 (51%)*	difference	
	n (%)	n (%)	n (%)	Effect size	*p-value*
Age in years, mean (SD)	48.2 (11.1)	46 (11.3)	50 (10.7)	0.365*	0.237
Gender				0.146	0.488
Female	32 (75)	17 (81.0)	15 (68.2)		
Male	11 (25)	4 (19.0)	7 (31.8)		
Race				0.066	0.755
White	28 (65.1)	13 (61.9)	15 (68.2)		
non-White	15 (34.9)	8 (38.1)	7 (31.8)		
Years of education, mean (SD)	14.6 (2.8)	14 (2.5)	15 (3.2)	0.254	0.413
Marital Status				0.451*	0.033
Married	20 (46.5)	6 (28.6)	14 (63.6)		
Single	11 (25.6)	9 (42.9)	2 (9.1)		
Widowed	1 (2.3)	1 (4.8)	0 (0.0)		
Divorced/Separated	11 (25.6)	5 (23.8)	6 (27.3)		
Employment Status				0.367*	0.122
Disability	30 (69.8)	12 (57.1)	18 (81.8)		
Working/Studying	7 (16.3)	5 (23.8)	2 (9.1)		
Retired	3 (7.0)	1 (4.8)	2 (9.1)		
Other	3 (7.0)	3 (14.3)	0 (0.0)		
Psychology appt scheduled at BL				0.050	1.00
No appt	27 (64.3)	13 (61.9)	14 (66.7)		
Yes appt	15 (35.7)	8 (38.1)	7 (33.3)		
Cancer type				0.162	0.771
breast	12 (27.9)	7 (33.3)	5 (22.7)		
cervical	7 (16.3)	3 (14.3)	4 (18.2)		
head/neck	5 (11.6)	3 (14.3)	2 (9.1)		
Other	19 (44.2)	8 (38.1)	11 (50.0)		
Urbanicity				0.124	0.537

	All participants	INT	TAU	Between-group	
	N=43 (100%)	*n=21 (49%)*	*n=22 (51%)*	difference	
	n (%)	n (%)	n (%)	Effect size	*p-value*
Urban	26 (60.5)	14 (66.7)	12 (54.5)		
Rural	17 (39.5)	7 (33.3)	10 (45.5)		
Living arrangements				0.440*	0.015
partner no children	12 (27.9)	2 (9.5)	10 (45.5)		
partner with children	9 (20.9)	4 (19.0)	5 (22.7)		
Other	22 (51.2)	15 (71.4)	7 (31.8)		
Existing Diagnosis – Depression				0.208	0.223
Yes	18 (41.9)	11 (52.4)	7 (31.8)		
No	25 (58.1)	10 (47.6)	15 (68.2)		
Existing Diagnosis – Anxiety				0.066	0.747
Yes	13 (30.2)	7 (33.3)	6 (27.3)		
No	30 (69.8)	14 (66.7)	16 (72.7)		
PHQ-9, mean (SD)	13.9 (5.56)	13 (6.1)	14 (7.1)	0.120	0.696
MDASI sadness scale, mean (SD)	5.9 (3.33)	6 (3.8)	6 (2.8)	0.126	0.681
Psychological Symptom Identification (n= 18,22)	17.7 (3.9)	18.4 (2.9)	17.1 (4.6)	-0.333	0.286
Psychological Distress (n=18,22)	17 (9.2)	16 (10.1)	17 (8.6)	0.066	0.846
Psychological Complaints (n=18,22)	9 (5.6)	8 (5.4)	10 (5.8)	0.304	0.343
Somatic Complaints (n=18,22)	11 (4.5)	11 (4.4)	11.0 (4.7)	-0.022	0.945
Unable to complete daily activities, mean (SD)	13 (10.4)	13 (9.4)	13 (11.6)	0.885*	0.096
Spent all or most of day in bed, mean (SD)	8 (9.2)	8 (8.0)	8 (10.5)	0.846*	0.456
Follow-up visit complete				0.280*	0.108
Yes	40 (93)	16 (84.2)	24 (100)		
No	3 (7)	3 (15.8)	0 (0)		

* Indicates >.2 = relevant difference for categorical variables and >.35 = relevant difference for continuous variables

Table 2 describes the differences between patients that enrolled in the study compared to those that did not. Participants that enrolled were slightly younger, more racially diverse, more likely to be divorced/separated, more likely to have breast cancer, and more likely to have a diagnosis of depression compared to those that did not enroll.

Table 3 outlines the un-adjusted outcomes (not controlled for propensity score) including the direction of change. Table 4 outlines the primary adjusted outcomes. Forty participants completed baseline and follow-up (Intervention=18; TAU=22). Follow-up visits were completed in an average of 54 days (range = 23-153 days) from baseline, which is 24 days on average from their first available follow-up interview date. Table 5 outlines the categorical analysis results of change for each of the attitude questions. Small to medium effect sizes were observed for three of the depression literacy constructs in the logistic analysis: correct depression symptom identification (OR=2.0, 95% CI=0.296-13.511), likelihood to seek MH care from professionals: counselors (OR=4.059, 95% CI=0.388-42.491), psychiatrists (OR=4.2, 95% CI=0.397-44.4), social workers (OR=4.2, 95% CI=0.397-44.401), and improved attitudes toward individuals with severe depression: "People with severe depression make good employees" (OR=2.556, 95% CI=0.214-30.469) and ‘I disagree people with severe depression perform poorly as parents" (OR=15.333, 95% CI=1.711-137.404). These improvements were only detected in the individual item analysis and did not hold in their corresponding MH literacy construct scale scores.

In terms of psychological symptom complaints, both groups demonstrated some improvement in their psychological distress rates at follow-up. Intervention participants reported small to medium effects size in their decreased frequency of somatic complaints (M=-1.7, SE=1.68, d=-0.378); however, TAU participants reported decreased psychological complaints (M= 2.3, SE=1.51, d=0.411). Finally, TAU patients had a significant increase in days spent in

bed compared to a stagnant report by the intervention group (M=-3.0, SE=3.36, d=-0.319); conversely, a similar level of improvement was found for TAU group in increased days able to complete daily activities (M=4.1, SE=3.1, d=0.39).

Table 2: Non-Enrolled v. Enrolled Participant Characteristics					
	All participants	Enrolled	Not Enrolled	Between-group	
	N= 78 (100%)	*n= 44 (100%)*	*n= 34 (100%)*	difference	
	n (%)	n (%)	n (%)	Effect size	*p-value*
Age in years, mean (SD)	50 (14)	48 (11)	53 (16)	0.365*	0.107
Gender				0.049	0.798
Female	57 (73)	33 (75)	24 (71)		
Male	21 (27)	11 (25)	10 (29)		
Race				0.258*	0.033
White	59 (76)	29 (66)	30 (88)		
non-White	19 (24)	15 (34)	4 (12)		
Marital Status				0.313*	0.054
Married	40 (51)	21 (48)	19 (56)		
Single	23 (30)	11 (25)	12 (35)		
Widowed	3 (4)	1 (2)	2 (6)		
Divorced/Separated	12 (15)	11 (25)	1 (3)		
Cancer type				0.321*	0.045
breast	18 (23)	12 (27)	6 (18)		
cervical	7 (9)	7 (16)	0 (0)		
head/neck	11 (14)	5 (11)	6 (18)		
Other	42 (54)	20 (46)	22 (65)		
Existing Diagnosis - Depression				0.216*	0.086
Yes	25 (32)	18 (41)	7 (21)		
No	53 (68)	26 (59)	27 (79)		
Existing Diagnosis – Anxiety	56 (72)			0.091	0.458
Yes	22 (28)	14 (32)	8 (24)		
No	56 (72)	30 (68)	26 (77)		
PHQ-9, mean (SD)	14 (6.1)	14 (7)	14 (6)	0	0.891
MDASI sadness scale, mean (SD)	5 (3.4)	6 (3)	4 (3)	-0.588	0.04

* Indicates >.2 = relevant difference for categorical variables and >.35 = relevant difference for continuous variables

Table 3. Unadjusted Estimates of Intervention Effects for Continuous Outcomes

	Baseline (n=40)			Follow-Up (n=40)		Change				
	INT (n=18)	TAU (n=22)		INT (n=18)	TAU (n=22)	**INT**	**TAU**	**Between-Group Difference**		
Outcome	Mean (SD)	Mean (SD)	Pooled SD	Mean (SD)	Mean (SD)	**Mean (SD)**	**Mean (SD)**	**Mean (SE)**	**Effect size**	***p-value***
Depression Identification Score	18.4 (2.9)	17.1 (4.6)	3.9	19.1 (4.4)	17 (4.3)	0.7 (4.4)	-0.1 (2.5)	0.81 (1.1)	0.208	0.469
Professional Help Seeking Score	5.0 (2.6)	5.6 (1.7)	2.2	3.9 (1.6)	4.3 (1.1)	-1.1 (2.5)	-1.2 (1.3)	0.17 (0.6)	0.077	0.791
Self-Help Seeking Score	3.0 (1.9)	2.5 (1.7)	1.8	2.8 (1.6)	2.2 (1.4)	-0.2 (1.4)	-0.3 (1.7)	0.05 (0.5)	0.028	0.918
Attitude Score	9.6 (3.5)	9.6 (2.7)	2.9	8.9 (3.3)	8.8 (2.5)	-0.9 (3.0)	1.0 (2.5)	0.20 (0.9)	0.069	0.834
Psychological Distress Score	16.3 (10.1)	16.9 (8.6)	9.2	14.6 (9.8)	13.1 (6.7)	-1.7 (6.4)	-3.8 (4.7)	2.06 (1.8)	0.225	0.313
Somatic Complaints Score	11.1 (4.4)	11.0 (4.7)	4.5	9.2 (4.8)	9.8 (5.3)	-1.9 (4.5)	-1.2 (4.8)	-0.8 (1.5)	-0.178	0.595
Psychological Complaints Score	7.8 (5.4)	9.5 (5.8)	5.6	7.2 (6.0)	7.2 (5.3)	-0.6 (5.2)	-2.3 (3.1)	1.7 (1.3)	0.304	0.216
Unable to complete daily activities	12.6 (9.2)	13.2 (11.6)	10.5	12.4 (9.1)	10.4 (11.0)	-0.2 (10.4)	-2.8 (6.5)	2.6 (2.7)	0.248	0.016
Spent all/most of day in bed	8.9 (8.3)	7.7 (10.5)	9.4	8.2 (7.4)	10.1 (10.1)	-0.6 (4.8)	2.4 (11.6)	-3.0 (2.9)	-0.319	0.107

Un-adjusted binary outcome variables

					Improvement					
	Baseline (n=40)		Follow-Up (n=40)					**95% CI**		
Outcome	INT (n=18)	TAU (n=22)	INT (n=18)	TAU (n=22)	**INT**	**TAU**	**Odds Ratio**	**Lower**	**Upper**	***p-value***
high Depression Literacy, n (%)	13 (72)	17 (77)	14 (82)	15 (71)	5 (29.4)	4 (19.0)	1.771	0.392	8.002	0.458
high OCD Literacy, n (%)	11 (65)	12 (55)	13 (77)	10 (48)	3 (19.0)	1 (4.8)	3.000	0.483	18.648	0.239
Correct Depression Rates, n (%)	10 (56)	12(55)	10 (56)	9 (41)	10 (55.6)	12 (54.5)	2.000	0.296	13.511	0.477

Change = Follow-Up – Baseline

Difference in change = INT – TAU

Table 4. Covariate-Adjusted Estimates of Intervention Effects					
	Covariate-Adjusted Change				
	INT	TAU	Between-Group difference		
Outcome	Mean (SE)	Mean (SE)	Mean (SE)	Effect size	*p-value*
Depression Identification Score	0.88 (0.9)	-0.22 (0.8)	1.1 (1.3)	0.282	0.395
Professional Help Seeking Score	-0.90 (0.5)	-1.4 (0.4)	0.45 (0.7)	0.205	0.516
Self-Help Seeking Score	-0.44 (0.4)	-.09 (0.3)	-0.3 (0.5)	-0.167	0.525
Attitude Score	-0.8 (0.8)	-0.8 (0.7)	0.4 (1.1)	0.138	0.975
Psychological Distress Score	-1.64 (1.4)	-3.95 (1.3)	2.3 (2.0)	0.251	0.260
Somatic Complaints Score	-2.36 (1.2)	-0.70 (1.1)	-1.7 (1.7)	-0.378*	0.331
Psychological Complaints Score	-0.28 (1.1)	-2.55 (0.9)	2.3 (1.5)	0.411*	0.140
Unable to complete daily activities	0.67 (2.1)	-3.46 (1.9)	4.1 (3.1)	0.390*	0.184
Spent all or most of day in bed	-0.63 (2.4)	2.4 (2.1)	-3.0 (3.4)	-0.319*	0.376
Adjusted binary outcome variables					
			95 % CI		
Outcome		Odds Ratio	Lower	Upper	*p-value*
high Depression Literacy, n (%)		1.372	0.266	7.07	0.705
high OCD Literacy, n (%)		2.130	0.322	14.098	0.433
Correct Depression Rates, n (%)		1.826	0.207	16.107	0.588

* Indicates relevant difference of effect size > 0.20 for continuous variables / OR>1.89 (INT) or <0.53 (TAU) for categorical variables
Difference in change = INT – TAU

Cohen's D effect size

Covariate = Propensity Score

Table 5. Estimates of Intervention Effects for Attitude Variables										
					Improvement					
	Baseline (n=40)		**Follow-Up (n=40)**					95% CI		
Outcome	INT (n=18)	TAU (n=22)	INT (n=18)	TAU (n=22)	INT	TAU	Odds Ratio	Lower	Upper	*p-value*
Improvement w/ Professional help, n (%)	18 (100)	21 (96)	17 (94)	19 (86)	0 (0)	1 (5)	0.579^	0.049	6.897	0.665
Improvement w/o Professional help, n(%)	10 (56)	10 (46)	9 (50)	10 (46)	1 (6)	6 (27)	0.157*	0.017	1.451	0.103
Looked for Information	11 (61)	15 (38)	13 (33)	17 (43)	4 (22)	2 (5)	2.000*	0.296	13.511	0.477
Likely to see:										
Counselor	16 (89)	21 (96)	17 (94)	21 (96)	2 (11)	0 (0)	4.059^*	0.388	42.491	0.242
PCP	15 (83)	21 (96)	16 (89)	18 (82)	3 (17)	0 (0)	5.750^*	0.587	56.346	0.133
Pharmacist	6 (33)	8 (36)	3 (17)	5 (23)	0 (0)	1 (5)	0.579^	0.049	6.897	0.665
Psychiatrist	13 (72)	20 (91)	14 (78)	19 (86)	3 (17)	1 (5)	4.20*	0.397	44.400	0.233
Psychologist	14 (78)	19 (86)	15 (83)	20 (91)	2 (11)	2 (9)	1.250	0.158	9.879	0.832
Social Worker	9 (50)	15 (68)	8 (44)	12 (55)	3 (17)	1 (5)	4.200*	0.397	44.401	0.233
Unlikely to not seek help	15 (83)	20 (91)	16 (89)	22 (100)	2 (11)	0 (0)	4.059^*	0.388	42.491	4.059
Acupuncturist	3 (17)	3 (14)	3 (17)	2 (9)	1 (6)	2 (9)	0.588	0.049	7.067	0.676
Clergy	13 (72)	14 (64)	13 (72)	14 (64)	2 (11)	2 (9)	1.250	0.1585	9.879	0.832
Family	10 (56)	9 (41)	11 (61)	9 (41)	3 (17)	1 (5)	4.200	0.397	44.401	0.233
Friends	14 (78)	11 (50)	10 (56)	12 (55)	0 (0)	5 (23)	0.159^	0.017	1.444	0.102
Herbalist	5 (28)	5 (23)	3 (17)	2 (9)	0 (0)	0 (0)	1.211^	0.071	20.67	0.895
Personal Trainer/Relaxation Instruct	7 (39)	10 (46)	10 (56)	9 (41)	3 (17)	5 (23)	0.680	0.139	3.337	0.635
Traditional Healer	2 (11)	3 (14)	0 (0)	1 (5)	0 (0)	1 (5)	0.579^	0.049	6.897	0.665
Likely to Discriminate against depression:										
Insurance/Financial Inst	9 (50)	10 (46)	8 (44)	8 (36)	2 (11)	3 (14)	1.263	0.187	8.547	0.810
Government Agency	5 (28)	9 (41)	6 (33)	6 (27)	2 (11)	2 (9)	0.800	0.101	6.329	0.832
Hospital	5 (28)	6 (27)	5 (28)	4 (18)	2 (11)	3 (14)	1.263	0.187	8.547	0.810
Strangers	15 (83)	21 (96)	14 (78)	15 (68)	2 (11)	1 (5)	0.381*	0.032	4.587	0.447
Doctor	6 (33)	4 (18)	4 (22)	3 (14)	1 (6)	1 (5)	0.810	0.047	13.889	0.884
Employer	13 (72)	16 (73)	13 (72)	13 (59)	2 (11)	2 (9)	0.800	0.101	6.329	0.832

	Baseline (n=40)		Follow-Up (n=40)		Improvement					
								95% CI		
Outcome	INT (n=18)	TAU (n=22)	INT (n=18)	TAU (n=22)	INT	TAU	Odds Ratio	Lower	Upper	*p-value*
Family	5 (28)	10 (46)	6 (33)	10 (46)	3 (17)	3 (14)	0.789	0.139	4.484	0.790
Friends	8 (44)	7 (32)	6 (33)	7 (32)	1 (6)	4 (18)	3.774*	0.383	37.037	0.255
I agree that people with severe depression are:										
Dangerous to others	8 (44)	15 (68)	5 (28)	11 (50)	4 (22)ł	6 (27)	0.762	0.178	3.262	0.714
Hard to talk to you	16 (89)	17 (77)	12 (67)	17 (77)	5 (28)ł	4 (18)	1.731	0.388	7.725	0.472
Often artistic	11 (61)	14 (64)	14 (78)	15 (68)	3 (17)	4 (18)	0.900	0.173	4.669	0.90
Productive when well	15 (83)	19 (86)	16 (89)	22 (100)	3 (17)	3 (14)	1.267	0.223	7.199	0.790
Have themselves to blame	1 (6)	3 (14)	4 (22)	3 (14)	0 (0)ł	1 (5)	0.579^	0.049	6.897	0.665
Good employees when well	16 (89)	22 (100)	17 (94)	21 (96)	1 (6)	0 (0)	2.556^*	0.214	30.469	0.458
Perform poorly as parents	12 (67)	5 (23)	7 (39)	7 (32)	7 (39)ł	0 (0)	15.333^*	1.711	137.400	0.015
Try even harder when well	18 (100)	21 (96)	15 (83)	19 (86)	0 (0)	0 (0)	1.2116	0.071	20.670	0.895
Should not have children to not pass it on	2 (11)	1 (5)	1 (6)	4 (18.2)	1 (5.6)ł	1 (5)	1.235	0.072	21.241	0.884
Should pull themselves together	7 (39)	12 (55)	7 (39)	8 (36.4)	3 (16.7)ł	4 (18)	0.900	0.173	4.669	0.900

* Indicates relevant difference ≥ 1.89 for INT group or ≤0.53 for TAU group

ł negative change

^Agresti-Coull method used for estimating odds ratio with 0 change cells

CHAPTER 4

DISCUSSION

The study aimed to: (a) assess the feasibility of implementation of a one-time psychoeducation intervention, focused on depression literacy with depressed palliative outpatients with cancer, and (b) assess the efficacy of the intervention beyond treatment as usual. The intervention focused on educating participants about depression and cancer, as well as their individual depression severity, self-help and professional ways to improve their mood, seek information, and monitor their depression symptoms overtime. The intervention materials were based on the IMPACT patient brochure and were used in session to guide discussion during the one hour, in-person visit. All patients completed two assessment interviews over the telephone at baseline and one month follow-up. The outcomes were designed to assess patients' MH literacy, psychological distress, and disability.

In terms of feasibility, 76 patients were eligible and able to be contacted by study staff. Of those, 43 enrolled, 24 declined, and 9 agreed but did not enroll. Fifty-seven percent of participants contacted agreed to participate, and those that enrolled were more likely to have a documented diagnosis of depression or anxiety in their medical record. In concordance with Kadan-Lottick et al.'s findings,[18] this may suggest that when patients are aware they have depression, they are more likely to be accepting of help and information, even in the form of research. This is not otherwise explained by severity of depression, because the group

differences in depression screening score did not differ. This speaks to the importance of providers prioritizing conversations related to MH as well physical health with their patients.

The fact that about 57% enrolled compared to 43% that did not, can also be understood in terms of the population. By definition, palliative patients are medically frail or medically complicated and often times are overloaded with medical visits or health concerns. That withstanding, in spite of their medical frailness, palliative patients were generally accepting of addressing their MH, simultaneously with physical health need.

The TAU participants were more likely to complete the study than intervention participants. This may be attributed to the added burden of the in-person intervention visit on this already medically inundated and frail population, because in comparison, the TAU group only had to complete the two telephone assessment interviews. This may speak to a need for integrating such an intervention into already existing medical appointments or through alternate modalities, such as over the telephone, in order to improve uptake of the information, while decreasing patient burden.

In terms of efficacy, modest improvements were found for the intervention group when compared to the TAU group in their knowledge, help seeking, and attitudes toward depression. Specifically, knowledge in their ability to accurately identify depression symptoms improved. They also reported greater likelihood in help seeking from counselors, psychiatrists, and social workers, if they thought they were experiencing depression. Their attitudes toward severe depression also improved in the areas of occupational and parental performance. These improvements were only detected in the individual item analysis and did not hold in their

corresponding MH literacy construct scale scores. The individual items demonstrating clinically relevant effects were modest, but support the rationale for further investigation.

Overall, both groups demonstrated some minor improvement in their self-reported mental health. Small to medium clinical effects were found in improving participants reported somatic and psychological symptoms. Intervention participants reported fewer somatic complaints at follow-up and TAU participants reported fewer psychological complaints. Overall, both groups reported less psychological distress. The lack of systematic patterns of these results may be due to the underpowered, multiple testing nature of the feasibility study, or there could be another explanation future research may clarify.

Intervention participants reported no change in the number of days they spent in bed, as compared to the TAU group, that reported an increase in days spent in bed. One component of the intervention was focused on behavioral activation. Participants created a list of activities they would like to initiate in the future and engaged in discussion for how to integrate these activities in their life. If they followed through on these goals at least to some degree (not measured in this study) being more activated could have decreased their psychological distress and improved their overall activity level. Changes in participation in meaningful activity should be measured in future research.

It should also be considered that palliative care is a specialized medical program designed to address physical and mental aspects of disease management, and is therefore an intervention beyond usual cancer treatment. Therefore, the mixed results of depression literacy, psychological distress, and disability between groups may demonstrate improvement from the intervention in some domains and improvement in care received in palliative care for other domains. In

conducting a similar study with an oncology TAU group, results may be more likely to demonstrate the strict intervention effect without the confounding of palliative treatment.

Limitations

Ability to truly understand the effects of this intervention and the mixed results of the study overall is limited by the sample size. A larger study would allow for significance testing, adjustment for multiple testing, and further examination of intervention effects. Also, this short-term study did not evaluate effects on help-seeking from providers across time and follow-up on behavioral activation activities. It would be interesting to examine the effects of giving patients the knowledge of severity of their depression and subsequent treatment options, and evaluate their help-seeking behaviors across time. Longitudinal design would also require an increase in sample size.

As noted above, intervention participants were less likely to complete the study than TAU participants, although it should be noted that only three intervention participants were lost to follow-up. Decreasing patient burden through alternative implementation strategies may improve uptake. Maintaining the limited contact intervention is appealing in considering feasibility of execution in their medical care setting; however, if the information could be broken up in smaller components and delivered across multiple clinic visits, without requiring an additional visit, patients may be more likely to enroll and complete the intervention.

Until very recently, measurement of MH literacy has lacked uniformity and the benefit of psychometric integrity across time. This study was limited by the measurement and multiple testing. Future studies would benefit from the use of a newly developed outcome measure of MH literacy called the Mental Health Literacy Scale.[58] This would improve upon the outcomes used

in this study by limiting the number of outcomes tested as it is a 35 item univariate scale with good internal and test-retest reliability.

Finally, there are limitations related to generalizability. The ability of this intervention to be taught and delivered effectively by multiple interventionists with varying backgrounds and level of experience is unknown due to the one interventionist design in this feasibility study. Also, increasing diversity in the geographic and population reach would increase the generalizability of the findings.

Future Implications

The objectives in determining feasibility and change in depression literacy were met for this one-time psychoeducation intervention with palliative cancer outpatients. Uptake of the intervention illustrated overall openness from patients to enroll in a mental health intervention; especially when they had a diagnosis of depression. Comparison analysis illustrated improvement in constructs of depression literacy including help seeking behaviors and attitudes of the severely depressed. This suggests grounds for further investigation of this intervention, potentially delivered in small "doses" during standard clinic visits, as a promising avenue for affecting positive change in depression management within this high risk population.

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APPENDICES

Appendix Table of Contents:

APPENDIX 1

VIGNETTES

Vignettes A

Scenario 1:

Let's imagine that for the last 3 months, you have not been able to shake the feeling of being down in the dumps. You have lost your appetite and have been waking up every night a couple of hours earlier than usual without being able to go back to sleep. You are tired all the time. Last week you almost caused a serious accident because you were having trouble concentrating.

1. Would this be a problem for you?

a. If "Yes": Do you have a name for this problem?

1. If "Yes": What name would you give this problem?

b. If "No": Tell me about what you think is going on with you in this scenario?

_____

_____

_____

Scoring:

All answers that included 'depression', 'depressed', 'depressive' = high depression literacy.

All answers coded 'not a problem' and any other label that does not include a form of the word 'depression' = low depression literacy.

*If a participant provides more than one label, their response will be coded as high depression literacy if any of those labels meet the above criteria; otherwise code the response as low depression literacy.

Scenario 2:

Thoughts of bad things happening often pop-up in your head. For example, you have intrusive thoughts that you left the stove on and your house is on fire. To feel better, you drive back home to check that the stove is off. You also believe that there are germs on things and that touching them will make you sick. Therefore, you wash your hands until they feel "just right". You feel like your thoughts and urges have control over you and you spend much of your day trying to prevent bad things from happening.

1. Would this be a problem for you?

a. If "Yes": Do you have a name for this problem?

1. If "Yes": What name would you give this problem?

b. If "No": Tell me about what you think is going on with you in this scenario?

_____
_____
_____

Scoring:

All answers that included 'Obsessive compulsive Disorder', 'OCD', 'Obsessions' = Low MH literacy.

All answers coded 'not a problem' and any other label than listed above = High MH literacy.

*If a participant provides more than one label, their response will be coded as high MH literacy if at least one of those labels meet the above criteria; otherwise code the response as low MH literacy.

Vignettes B

Scenario 1:

You have difficulty with your front door. Whenever leaving your house, you think that you have not locked the door and feel compelled to return to the door over and over again to check that it is locked. You also feel unable to leave your home unless you look out your front windows five times, to check that they are not broken. Consequently, it can take you an extra hour to leave your house and when you leave you are still concerned the door is not locked. Recently, you saw a sign in the street warning about open manhole covers during construction. Since then, you have become preoccupied with ensuring that all the manhole covers in the street are closed, that they are lying flat and level with the road, and that there are no gaps between the covers and the holes. You check manhole covers whenever you go are out and you find yourself worrying about them throughout the day. These worries increasingly consume your thoughts and those around you have become concerned.

1. Would this be a problem for you?

a. If “Yes”: Do you have a name for this problem?

1. If ”Yes”: What name would you give this problem?

b. If “No”: Tell me about what you think is going on with you in this scenario?

_____

_____

_____

Scoring:

All answers that included 'Obsessive compulsive Disorder', 'OCD', 'Obsessions' = Low MH literacy.

All answers coded 'not a problem' and any other label than listed above = High MH literacy.

*If a participant provides more than one label, their response will be coded as high MH literacy if at least one of those labels meet the above criteria; otherwise code the response as low MH literacy.

Scenario 2:

For the past two weeks, you have been feeling really down. You wake up in the morning with a flat, heavy feeling that sticks with you all day. You aren't enjoying things the way you normally would. In fact, nothing gives you pleasure. Even when good things happen, they don't seem to make you happy. You push on through your days, but it is really hard. The smallest tasks are difficult to accomplish. You find it hard to concentrate on anything. You feel out of energy and out of steam. And even though you feel tired, when night comes you can't go to sleep. You feel pretty worthless and very discouraged. Your family has noticed that you haven't been yourself for the last month and that you have pulled away from them. You just don't feel like talking.

1. Would this be a problem for you?

a. If "Yes": Do you have a name for this problem?

    1. If "Yes": What name would you give this problem?

b. If "No": Tell me about what you think is going on with you in this scenario?

_____
_____
_____

Scoring:

All answers that included 'depression', 'depressed', 'depressive' = high depression literacy.

All answers coded 'not a problem' and any other label that does not include a form of the word 'depression' = low depression literacy.

*If a participant provides more than one label, their response will be coded as high depression literacy if any of those labels meet the above criteria; otherwise code the response as low depression literacy.

APPENDIX 2

INTERNATIONAL DEPRESSION LITERACY SURVEY

Depression Literacy Questionnaire

The following questions are meant to ask about your knowledge of different health problems. The survey will take only a few minutes. If I go too fast or you would like me to repeat any questions, please let me know. If there is a question you do not feel comfortable answering, let me know and we can skip it.

A. RECOGNITION

Q1a. I am going to read a list of items. I would like you to indicate which of the following you consider to be symptoms of depression?

◯ Being sad, down or miserable

◯ Feeling Frustrated

◯ An upset stomach

◯ Thinking others are "out to get me"

◯ Thinking "there is nothing I cannot do"

◯ Feeling overwhelmed

◯ Thinking "It's all my fault"

◯ Feeling disappointed

◯ Hearing voices in my head

◯ Being irritable or cranky

◯ Thinking "I'm a failure"

◯ Weight loss

◯ Substance Use

◯ Feeling Guilty

◯ Sleep disturbance

◯ Headaches and muscle pains

◯ Elated/euphoric

◯ Thinking "Life is not worth living"

◯ Binge drinking on alcohol

◯ Having no confidence

◯ Feeling tired all the time

◯ Poor appetite

◯ Nightmares

◯ Thinking "I'm worthless"

◯ Reliving an event that happened in the past

◯ Feeling sick and run down

◯ Being unhappy

◯ Laziness

◯ Thinking "Nothing good ever happens to me"

◯ Being indecisive

◯ Don't know

◯ Other (please specify):

_____

Q1b. I am going to read another list of items. I would like you to indicate which of the following you consider to be typical of people with depression?

◯ Forgetting the names of people they know well

◯ Be unable to concentrate or have difficulty thinking

◯ Not get things done at school/work

◯ Weak-minded

◯ Experience discrimination

◯ Stop going out

◯ Very organized with their time/daily schedule

◯ Have relationship or family problems

◯ Have relationship or family breakdown

◯ Repetitive/constant exercise

◯ Become dependent on alcohol, drugs or sedatives

◯ Lack self-care (e.g. have a change in their personal hygiene habits)

◯ Attention seeking

◯ Lose their job

◯ Have suicidal thoughts or behaviors

◯ Stop doing things they enjoy

◯ Forgetting how to do everyday tasks such as washing clothes

◯ Develop new physical health problems

◯ Withdraw from close family and friends

◯ Don't know

◯ Other (please specify):

_____
_____

Q2. What proportion of people do you think experience depression at some point in their lives?

◯ 1 in 50 people

◯ 1 in 20 people

◯ 1 in 4 people

◯ Don't know

Q3. What chance do you think there is that you, or someone very close to you, will experience depression at some point in their lives?

◯ Zero to 25%

◯ 26 to 50%

◯ 51 to 75%

◯ 76 to 100%

◯ Don't know

◯ Other (please specify): _____

B. KNOWLEDGE

Q4. I am going to read you a list. I would like you to tell me what would be the one MOST likely result if you, or someone very close to you, received professional help for depression (e.g. from a doctor, psychologist, psychiatrist or other counselor) (one answer only)?

◯ Fully recover

◯ Fully recover but then have the illness come back again

◯ Have some improvement

◯ Have some improvement but then get worse again

◯ Have no improvement

◯ Get worse

◯ Don't know

Q5. I am going to read you and list. I would like you to tell me what would be the one MOST likely result if you, or someone very close to you, did NOT receive professional help for depression (one answer only)?

◯ Fully recover

◯ Fully recover but then have the illness come back again

◯ Have some improvement

◯ Have some improvement but then get worse again

◯ Have no improvement

◯ Get worse

◯ Don't know

◯ Other (please specify):

_____

The word depression often means different things to different people. In the following questions, what we mean by "depression" is an illness that is more severe, more prolonged and more disabling than normal sadness, grief or other normal feelings of sadness or loss.

Q6a. I am going to read off a list to you. I would like you to rate each item on a scale that ranges from definitely unlikely, probably unlikely, probably likely, definitely likely or don't know. If you thought you might be experiencing depression, how likely would you be to seek help from each of the following professionals (please rate all 9 categories)?

	Definitely Unlikely	Probably Unlikely	Probably Likely	Definitely Likely	Don't Know
a. Counselor	◯	◯	◯	◯	◯

	Definitely Unlikely	Probably Unlikely	Probably Likely	Definitely Likely	Don't Know
b. Family or palliative care doctor	○	○	○	○	○
c. Pharmacist	○	○	○	○	○
d. Psychiatrist	○	○	○	○	○
e. Psychologist	○	○	○	○	○
f. Social worker	○	○	○	○	○
g. Welfare officer	○	○	○	○	○
h. No one / wouldn't seek help	○	○	○	○	○
i. Other (please specify):	○	○	○	○	○

_____

—

Q6b. I am going to read off a list to you. I would like you to rate each item on a scale that ranges from definitely unlikely, probably unlikely, probably likely, definitely likely or don't know. If you thought you might be experiencing depression, how likely would you be to seek help from each of the following people (please rate all 8 categories)?

	Definitely Unlikely	Probably Unlikely	Probably Likely	Definitely Likely	Don't Know
a. Acupuncturist	○	○	○	○	○
b. Clergy, priest or other religious person	○	○	○	○	○
c. Family	○	○	○	○	○
d. Friends	○	○	○	○	○
e. Naturopath or herbalist	○	○	○	○	○
f. Personal trainer, exercise manager or relaxation instructor (e.g. massage therapist, yoga or meditation teacher)	○	○	○	○	○
g. Traditional healer (e.g. Qigong master, shaman)	○	○	○	○	○

	Definitely Unlikely	Probably Unlikely	Probably Likely	Definitely Likely	Don't Know
h. Other (please specify): _____	◯	◯	◯	◯	◯

Q7. I am going to read off a list to you. I would like you to rate each of the following types of treatment for depression. Please indicate if you think they would be helpful, harmful, neither, haven't heard of it or don't know (please rate all 11 categories)?

	Harmful	Neither	Helpful	Never heard of it	Don't Know
a. Becoming more physically active (e.g. playing sport, walking, gardening)	◯	◯	◯	◯	◯
b. Changing your diet	◯	◯	◯	◯	◯
c. Having an occasional alcoholic drink	◯	◯	◯	◯	◯
d. Reading about people with similar problems and how they have dealt with them	◯	◯	◯	◯	◯
e. Reading self-help book(s)	◯	◯	◯	◯	◯
f. Taking antidepressant medications	◯	◯	◯	◯	◯
g. Taking natural remedies (e.g. vitamins)	◯	◯	◯	◯	◯
h. Taking sleeping tablets or sedatives	◯	◯	◯	◯	◯
i. Using brief counseling therapies (e.g. cognitive and/or behavioral therapies)	◯	◯	◯	◯	◯
j. Using long-term counseling	◯	◯	◯	◯	◯
k. Other (please specify): _____	◯	◯	◯	◯	◯

Q8a. Have you, or someone very close to you ever experienced depression?

◯ Yes (please go to Q8b)

◯ No (go to section C)

◯ Don't know (go to section C)

Q8b. Who was that?

◯ I experienced depression

◯ Someone very close to me experienced depression

Q8c. Did you, or someone very close to you receive any help for this?

◯ Yes (go to Q8d)

◯ No (go to section C)

◯ Don't know (go to section C)

Q8d. Who provided this help (Mark all that apply)?

◯ Counselor

◯ General or family doctor

◯ Pharmacist

◯ Psychiatrist

◯ Social worker

◯ Welfare officer

◯ Don't know

◯ Other (please specify): _____

Q8e. Did any of these other people provide help (Mark all that apply)?

◯ Acupuncturist

◯ Clergy, priest or other religious person

◯ Personal trainer or exercise manager

◯ Family

◯ Friends

◯ Naturopath or herbalist

◯ Relaxation instructor (e.g. massage therapist, yoga or mediation teacher)

◯ Traditional healer (e.g. Qigong master, shaman)

◯ Don't know

◯ Other (please specify): _____

Q8f. Where did you or the person close to you receive help for depression?

◯ Specialist mental hospital

◯ General medical hospital

◯ General or family doctor's rooms / clinic

◯ Specialist doctor's rooms or clinic (i.e. psychiatrist)

◯ Other medical specialist doctor's rooms or clinic (e.g. neurologist, cardiologist)

◯ Other counselor or therapist's rooms or clinic run by nurses or other professionals

◯ Don't know

◯ Other (please specify): _____

C. INFORMATION

Q9a. Have you ever looked for information about depression?

◯ Yes

◯ No (go to Section D)

Q9b. If YES, how did you get this information (mark all that apply)?

◯ Asked a doctor

◯ Asked a friend

◯ Asked a family member

◯ Bought a book or health magazine

◯ Called a helpline

◯ Contacted a community health center

◯ Contacted a mental health organization

◯ Printed information from pharmacies or medical center

◯ Searched the Internet

◯ Visited the library

◯ Television or radio

◯ Don't know

◯ Other (please specify): _____

D. PERCIEVED NEEDS

Q10a. Have you personally sought help from a general or family doctor for an emotional problem in the last 12 months?

◯ Yes

◯ No (go to Section E)

Q10b. The following questions ask whether you would like your general or family doctor to discuss with you any of the following kinds of help for common emotional problems such as feeling depressed or anxious. Your general or family doctor might offer to help you in this way, or you might prefer your general or family doctor to suggest an alternative source of help. You may already be getting this kind of help or you may not need to discuss this type of help.

	I would like my general or family doctor to discuss this kind of help with me	I don't need to discuss this kind of help	I am already getting this kind of help (either from my general or family doctor or somewhere else)
Information about emotional problems or getting treatment for these problems	◯	◯	◯
Medication or tablets to help you with emotional problems	◯	◯	◯
Counseling: including any kind of help to talk through your problems	◯	◯	◯

Q10c. Have any of the following reasons stopped you in the last few weeks, from getting any of these kinds of help, or from getting as much help as you may have needed (answer all that apply to you)?

◯ Not applicable, I haven't needed any of these kinds of help…

◯ I preferred to manage myself

◯ I didn't think anything would help

◯ I didn't know where to get help

◯ I was afraid to ask for help or what others would think of me

◯ I couldn't afford the money

◯ I asked but didn't get help

◯ I received the help I needed

E. ATTITUDES

The following questions ask about the experiences people with mental illness sometimes have. Discrimination here means that a person with depression is treated unfairly just because they have a mental illness, rather than for any other reason.

Q11. I am going to read off a list to you and would like you to rate each item on a scale that ranges from definitely unlikely, probably unlikely, probably likely, definitely likely or don't know. If you, or someone very close to you experienced depression, do you think you would be discriminated against by (please rate all 9 categories)?

	Definitely Unlikely	Probably Unlikely	Probably Likely	Definitely Likely	Don't know
a. A bank, insurance company or other financial institution	○	○	○	○	○
b. A government or other public welfare agency	○	○	○	○	○
c. A public or private hospital	○	○	○	○	○
d. Other people who don't know you well	○	○	○	○	○
e. Your doctor or other health professional	○	○	○	○	○
f. Your employer	○	○	○	○	○
g. Your family	○	○	○	○	○
h. Your friends	○	○	○	○	○
i. Other (please specify): _____	○	○	○	○	○

The following question asks about people with severe depression. By severe depression we mean a depressive illness that is so extreme and distressing that the person may require specialized medical treatment, or the impact of the depression on their lives is very large (the person may not be able to work or socialize).

strongly disagree, disagree, agree, strongly agree or don't know. To what extent do you agree or disagree with the following statements regarding people with severe depression (please rate all 10 categories)?

"People with severe depression …"	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
a. Are dangerous to others	◯	◯	◯	◯	◯
b. Are hard to talk to	◯	◯	◯	◯	◯
c. Are often artistic or creative people when they are well	◯	◯	◯	◯	◯
d. Are often very productive people when they are well	◯	◯	◯	◯	◯
e. Have themselves to blame	◯	◯	◯	◯	◯
f. Often make good employees when they are well	◯	◯	◯	◯	◯
g. Often perform poorly as parents	◯	◯	◯	◯	◯
h. Often try even harder to contribute to their families or work when they are well	◯	◯	◯	◯	◯
i. Shouldn't have children in case they pass on the illness	◯	◯	◯	◯	◯
j. Should pull themselves together	◯	◯	◯	◯	◯

F. DEPRESSSION ASSESSMENT

Q13. Please tell me how often, none of the time, a little of the time, some of the time, most of the time or all of the time, in the past 30 days ….

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
a. Did you feel tired out for no good reason	◯	◯	◯	◯	◯
b. Did you feel nervous	◯	◯	◯	◯	◯
c. Did you feel so nervous that nothing could calm you down	◯	◯	◯	◯	◯
d. Did you feel hopeless	◯	◯	◯	◯	◯
e. Did you feel restless or fidgety	◯	◯	◯	◯	◯
f. Did you feel so restless that you could not sit still	◯	◯	◯	◯	◯
g. Did you feel depressed	◯	◯	◯	◯	◯
h. Did you feel that everything was an effort	◯	◯	◯	◯	◯
i. Did you feel so sad that nothing could cheer you up	◯	◯	◯	◯	◯
j. Did you feel worthless	◯	◯	◯	◯	◯

Q14. Please tell me over the past few weeks how often, never or some of the time, a good part of the time or most of the time, have you been troubled by…

	Never	Some of the time	A good part of the time	Most of the time
a. Feeling nervous or tense?	◯	◯	◯	◯
b. Muscle pain after activity?	◯	◯	◯	◯
c. Feeling unhappy and depressed?	◯	◯	◯	◯
d. Needing to sleep longer?	◯	◯	◯	◯
e. Prolonged tiredness after activity?	◯	◯	◯	◯
f. Feeling constantly under strain?	◯	◯	◯	◯
g. Poor sleep?	◯	◯	◯	◯
h. Everything getting on top of you?	◯	◯	◯	◯
i. Poor concentration?	◯	◯	◯	◯
j. Tired muscles after activity?	◯	◯	◯	◯
k. Losing confidence?	◯	◯	◯	◯
l. Being unable to overcome difficulties?	◯	◯	◯	◯

Q15. During the last <u>month</u>:

a. How many days in total were you unable to carry out your usual daily activities, like going to work or school, fully?

_____ days

b. How many days in total did you stay in bed all or most of the day because of your illness or injury?

_____ days

APPENDIX 3

UA IRB APPROVAL

Office for Research

Institutional Review Board for the
Protection of Human Subjects

THE UNIVERSITY OF
ALABAMA
RESEARCH

April 17, 2014

Rebecca S. Allen, Ph.D.
Professor of Psychology
Center for Mental Health & Aging
The University of Alabama

Re: IRB Protocol # 14-012-ME
"A Brief Depression Literacy Intervention with an Outpatient Palliative Cancer Population"

Dr. Allen:

The University of Alabama Medical IRB recently met to consider your protocol. The medical IRB voted to table your protocol pending clarification of the issues outlined below.

1. The cover letter submitted indicates that a protocol application has been submitted to the UAB IRB at this time. Please provide the board with an update on the status of the IRB review at UAB. Also, please provide the board with a complete copy of the UAB IRB protocol/consent document for review along with a copy of the approval letter if approval has been received.

2. The protocol submitted to the UA IRB includes a request for a waiver of informed consent. The waiver indicated that this is being requested in order to use the UAB informed consent document in order to decrease burden of paperwork on participants. Since you do plan to obtain informed consent from participants using the UAB IRB approved consent document, you can remove the waiver request from the UA protocol. The section of the UA protocol outlining the consent process to be used should indicate that you will be using the UAB IRB approved consent document. As noted in item # 1 above, the UA IRB will need to be provided with a copy of the UAB informed consent document for review. This document should also provide the participant with contact information for the UA IRB.

3. Within the section of the protocol titled "Subject Recruitment Methods", language indicates that "data managers are able to program an electronic mail alert in the system that will notify the recruiter/investigator of the medical record numbers of patients that meet depression inclusion criteria". During review the board held discussion regarding the electronic transfer of protected health information (PHI) and had questions pertaining to the transfer. The questions pertained to whether or not the electronic transmission was encrypted for both the sending and receiving parties, the use of medical record numbers in this transfer, and whether or not potential participants would provide authorization or consent for this transfer. It was noted during discussion that many of these issues would likely be outlined within the UAB IRB protocol and submission of that documentation would provide clarification. Additionally, within the revised version of the UA IRB protocol please provide verification that the procedure outlined for the electronic transfer of PHI does meet the UAB requirements for this transfer.

Please highlight revisions made to the documents and include a letter indicating the page numbers where changes have been made.

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TOLL FREE (877) 820-3066

Please submit the requested information to Ms. Tanta Myles for review at Box 870127 within 60 days of the issue date of this letter. If the IRB does not receive a response to the requested revisions within 60 days, you will be required to submit a new application to the board for review. If you would like your application to be reviewed at the May 8, 2014 meeting, please submit your revised document to the Office for Research Compliance by **April 29, 2014**.

If I can be of further assistance please feel free to contact me.

Sincerely,

John C. Higginbotham, Ph.D., MPH
Medical IRB Chair
The University of Alabama