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Reducing Benzodiazepine Use in the Treatment of Anxiety in a Community Mental Health Setting

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Background and Significance

Anxiety disorders are among the most common mental health disorders in the United States according to the Substance Abuse and Mental Health Administration Services (SAMHSA), affecting nearly 18% of the adult population annually (SAMHSA, 2013). Modalities for the treatment of anxiety disorders shifted in the late 1980s and early 1990s because of concerns in the medical community regarding the risks of abuse and dependence engendered by the long-term use of benzodiazepines (Smith & Tett, 2010). The most common treatment approaches have included a combination of non-pharmacological interventions and medication approaches as endorsed in the United Kingdom in the seminal work of Dr. C. Heather Ashton (Ashton, 1994) and mirrored by the American Psychiatric Association in its own seminal work in the United States (APA, 1990.)

A consensus report was adopted by the American Psychiatric Association (APA) to limit the use of these agents and best practice models were adapted to guide prescribers (APA, 1990). These best practices included limiting benzodiazepines to short-term use due to their risk of tolerance and dependence (NICE, 2011). The use of benzodiazepines, according to a best practices model, should be limited to crisis intervention or to assist in the abatement of the most severe anxiety and panic symptoms, with the intent to concurrently prepare the patient for the work of learning to manage anxiety and panic (Ashton, 1994).

It is an accepted tenet that the extended use of these agents to treat anxiety encourages abuse and dependence and compromises the sobriety of individuals recovering from alcohol and

illicit drug dependencies (APA, 1990; Ashton, 1994). Additional risks inherent in the use of benzodiazepines occur when the drug is abruptly withdrawn or not available to an individual who has developed dependence include seizure activity, withdrawal symptoms, rebound anxiety and rebound hypertension (APA, 1990, p. 35). Recent research has also implicated the use of benzodiazepines in increased incidences of dementia (de Gage, et al. 2012).

Benzodiazepines continue to be prescribed often: 112.8 million benzodiazepine prescriptions were filled in 2007 (Cascade & Kaskali,, 2008). Data from 1987 indicates that this number was 10.9 million (Olfson & Pincus, 1994). According to the Centers for Disease Control (CDC) death rates attributable to overdoses more than tripled since 1990 (CDC, 2011). While prescription pain medications, primarily opiates, are responsible for three out of four prescription drug-related deaths, over half of those deaths involve concomitant use of benzodiazepines, cocaine and alcohol (CDC, 2011). The American Academy of Pain Medicine (AAPM) recently released a report based on CDC data indicating that 30% of prescription drug deaths result from an opioid-benzodiazepine combination (AAPM, 2013). The study by Bachuber, et al. (2016) noted that overdose deaths from benzodiazepines increased from .58 per 100,000 in 1996 to 3.07 per 100,000 in 2013.

For the past twenty years, the standard of care for the treatment of anxiety disorders has consisted of psychotherapeutic modalities: cognitive-behavioral therapy (CBT,) mindfulness and relaxation techniques, as well as other non-medication-focused treatments. The first-line approach, during this same time span, has also consisted of medications that target neurotransmitters believed to play major roles in the mediation of symptoms associated with anxiety disorders; these medications have included Selective Serotonin Re-uptake Inhibitors

(SSRIs,) Serotonin and norepinephrine re-uptake inhibitors (SNRIs,) GABAergic agents and other non-benzodiazepine anxiolytics.

In spite of this standard of practice (Magellan, 2012), the use of benzodiazepines has not significantly decreased. A recent study conducted by Bachhuber, Hennesey, Cunningham, and Starrels (2016), using data from the CDC, concluded that between 1996 and 2013, the number of filled prescriptions for benzodiazepines, in the adult population, rose from 4.1% to 5.6%. If actual practice deviates from established standards of practice, as the data supports, (Sanyal, Asbridge, Kisely, Sketris & Andreou, 2011), the reasons for this deviation must be explored and an attempt made to determine if there is a valid reason to alter the best practices approach. Conversely, if this deviation from care continues to exact the price of poor outcomes and abuse/dependence that has previously been established, practitioners must be encouraged to conform to these best practices.

Purpose

The purpose of this project is to develop and implement an evidence based pilot program that uses an internet-based, cognitive-behavioral program to successfully wean clients using benzodiazepines for anxiety disorders with minimal to no perceived participant distress and to reduce the risk of dependence, addiction, and overdose with these agents.

Literature Review

An initial search was conducted using the standard CINAHL nursing database. This initial search netted few germane research articles. Therefore, the search was broadened to include the following journal databases: Academic Search Premier; CINAHL, Health and Psychosocial Instruments, Health Source - Consumer Edition, Health Source: Nursing/Academic

Edition, MEDLINE, PsycARTICLES, Psychology and Behavioral Sciences Collection and PsycINFO. The Substance Abuse and Mental Health Services (SAMHSA) website was also searched for relevant scholarly articles, and resources.

Because the topic of interest included best practices models and practice guidelines, the following web-sites were also searched: National Institute of Health (NIH), National Institute of Mental Health (NIMH), American Psychiatric Nurses Association (APNA) policy papers, American Medical Association (AMA) policy papers, Kentucky Board of Nursing (KBN), and the National Guideline Clearinghouse.

Throughout the search, several search terms were used. Initially, basic terms such as "anxiety disorders", "benzodiazepines", "treatment of anxiety" were used. It was quickly apparent that these search terms were often too vague or too broad to garner relevant research studies. Therefore, numerous journal articles were reviewed and other terminology was used to refine the previous searches. Effective search terms included: "treatment of anxiety disorders in PTSD", "cognitive-behavioral therapy", and "mindfulness" among many others. The initial literature search was halted when saturation was reached.

Thirty-eight articles were determined to be relevant to this review. Of those articles, twelve contained randomized-controlled trials (RCTs). Of the studies that included RCTs, nine of those were integrated studies, consisting of quantitative and qualitative data. Because of the subjective nature of outcomes most commonly measured in psychiatric research, integrated studies often capture data that is difficult to quantify. Four of the studies included were descriptive studies and six were systematic literature reviews. Three articles meeting criteria for inclusion in this review were clinical guidelines. Also included in this review were two focus

groups study, an expert opinion paper, four post-hoc integrated studies, one criterion-standard study, and five descriptive studies.

The seminal work from the APA (1990) identified the inherent problems of addiction and dependence with long-term benzodiazepines and recommended that physicians alter their practices to consider the use of talk therapies as first-line modalities of care for the treatment of anxiety. It declines to make specific recommendations for time limits on the prescribing of benzodiazepines, possibly due to its reluctance to hinder the judgment of the individual physician's judgment. There are no follow-up publications or white papers by the APA that have addressed this practice standard since the 1990 publication. Another seminal work, this time from Great Britain, The Ashton Report (Ashton, 1994) set forth similar practice guidelines for psychiatrists, urging limited use of benzodiazepines and encouraging providers to employ more talk therapies as first-line courses of treatment for anxiety. Magellan (2012) published clinical guidelines promoting talk therapies such as CBT as the first line of treatment for individuals with anxiety disorders. It recommends talk therapies plus medications as first line treatments, but specifically attempts to dissuade providers from including long-term benzodiazepines within the definitions of first line medications.

Gosselin, Morin, Dugas, & Baillargeon (2006) demonstrated the positive benefits of CBT in their Canadian study. These researchers gathered a convenience sample, later randomized to groups, through media ads. The initial respondents (N=273) were screened for study inclusion. The criteria for study inclusion was based on individuals meeting the criteria for Generalized Anxiety Disorder, currently prescribed a benzodiazepine and expressing a willingness to discontinue treatment with those agents (N= 61). These participants were randomized to two groups: one group received usual care (n= 30) and the other group received CBT (n= 31). At the

end of the three month study, 74% of the group who received CBT had discontinued benzodiazepines versus 36% in the group receiving usual care. These findings supported the hypothesis that the addition of CBT to treatment for people with anxiety can increase the ability to wean them from these agents. Follow up anxiety screening using the Worry and Anxiety Questionnaire demonstrated continued benefits of CBT at the 6- and 12-month assessment points.

In an effort to locate existing research on current policy, laws, and statistical information related to the prescribing of controlled substances, specifically benzodiazepines, a literature search was pursued using Google Scholar, Google, and National Institute for Mental Health (NIMH) databases. This search netted sixteen germane articles. Of these sixteen articles, two were time series analyses of prescribing habits (Cunningham, Hanley, & Morgan, 2010; Dormuth, Miller, Huang, Mamdani., & Juurlink, 2012).One study was a prospective analysis. The remaining thirteen articles were white papers, statistical reports and laws pertaining to the prescribing of controlled substances in the United States, Great Britain, Ireland, Canada and Australia. Practice guidelines and statistical data from the World Health Organization (WHO) were also obtained.

Figures released by the Kentucky Injury Prevention and Research Center (2014) report that the number of overdose-related hospitalizations involving benzodiazepines in Kentucky in 2000 was 793; in 2013 that number was 1,686 (Svetla, Bunn, & Lambert, 2014). The cost of care for all drug overdose hospitalizations (of which benzodiazepines are the singular cause or contributory) rose from $21.1 million in 2000 to $129.3 million in 2012; total days of hospitalization days for overdoses in Kentucky rose from 10,385 in 2000 to 21,344 in 2012 (Svetla et al., 2014). The 2013 report issued by Trust for America's Health (TFAH) found that

Kentucky ranks third in the nation in drug overdose mortality and that a large proportion of those deaths are prescription drug related (TFAH, 2013). The same report, however, endorsed Kentucky as one of the leading states in its corrective planning to curb those deaths, including increased education for prescribers, increased real-time access to a controlled drug monitoring program and efforts to educate the public on the dangers of misuse of prescription drugs (Trust for America's Health, 2013).

In response to increasing deaths associated with prescription drug overdoses, primarily opiates but also benzodiazepine-only or combination overdoses that include benzodiazepines, the Kentucky Legislature adopted House Bill 1 (now KRS 218A) to hold prescribers more accountable for the prescribing of the agents (as well as psychostimulants) in 2013. Its purpose was to outline the requirements of prescribers to provide minimal assessment, documentation of need, review of the state's controlled reporting system [KASPER] and engaging in education with clients that is documented by written contracts between the patient and the prescriber, signifying the patient is aware of the conditions under which these controlled agents would be prescribed (Cohron, 2014; Parton, 2012).

Theoretical Framework

The recovery model provides the theoretical underpinning of this project (Anthony, 1993). The recovery model developed out of the "survivor" movement of the 1970s when a number of people with mental illnesses began to write about their experiences with institutionalized (whether inpatient or community) psychiatric care. These pioneers considered themselves survivors and ex-patients as they pulled away from traditional, pharmacological, and restrictive treatments. Initially, there was much opposition between these consumers and the

professionals who considered their labors to be minimized at best and vilified at the worst. Over the ensuing decades, these sides have come together in a less oppositional manner and have, over time, contributed to a body of knowledge that has formalized the recovery model as a conceptual framework.

The core belief of the recovery model is that people get better. Their illness is a reality and has changed their lives, forever. People move on and the illness does not have to remain a focus of their entire lives (Anthony, 1993). It is not a necessary result of mental illness to lose all the roles that people have achieved or strive to achieve. Recovery can concretely be interpreted as recovering valued roles: worker, student, parent, significant other, sibling, author, and so on. Any dreams that a person without a mental illness is entitled to, so is a person with a mental illness. As a result of the "take back our lives" focus of the originators of the recovery model, stakeholders in mental health (providers and consumers alike) have adopted a person-centered, respectful stance with those individuals who must deal with a mental illness that impacts all areas of their lives. A basic tenet of the recovery model is responsibility for self: "The recovery model emphasizes that responsibility for and control of the recovery process must be given in large part to the person who has the condition." (Frese, Stanley, Kress & Vogel-Scibilia, 2001). Mental health providers have gradually come to incorporate this model and its philosophy into day-to-day care, treatment planning and goal-setting.

Best practices treatment for anxiety, such as cognitive-behavioral therapy, are consistent with the recovery model. In CBT, the person is taught the tools to rethink, reframe and thus change their own behaviors in coping with anxiety- provoking thoughts and circumstances. Once taught, these tools cannot be un-taught and remain lifelong skills for the person. Conversely, the use of benzodiazepines inherently requires a consistent dependence on a prescriber so that the

prescriber can provide the "tool" to decrease anxiety in the form of a pill; and with benzodiazepines, the "choice" is much reduced for the consumer by the very nature of their mechanisms of action.

Methods and Procedures

Design. This was an evidence-based pilot project using a one-group, pre-test, post-test model.

Setting. This pilot project was conducted in an urban community mental health center in the southeastern United States that serves over 1,900 clients. This center serves adults with a full complement of mental illnesses, intellectual disabilities, substance use disorders, and other emotional and behavioral disturbances.

Population. The project coordinator (DNP student) identified three colleagues who voiced a willingness to participate in the recruitment of participants from their caseload of patients currently receiving benzodiazepines. A search was conducted using the agency's electronic prescribing software to obtain a list of active prescriptions for benzodiazepines prescribed by the three colleagues as well as the project coordinator. This resulted in a list of over 60 people. From that list, only individuals who met the criteria for the project were included. Excluded individuals were those with developmental disabilities, traumatic brain injuries and dementia. The rationale for this exclusion is the presumption that there may be limited ability on the part of these individuals to successfully access and retain the information available in the web-based CBT program. The resulting number of potential participants was 38.

All potential participants were invited into the project by the project coordinator, either in person or through a letter of invitation sent in advance of their next scheduled appointment with

their respective prescriber. In the letter, a brief introduction of information was made regarding the intended project and an invitation to discuss this opportunity with his or her prescriber at the next visit with the prescriber. The prescribers were asked by the project coordinator to follow up with these clients at their next scheduled visit to discuss the project further and to engage the project coordinator for further instruction if the patient evidenced any interest in engaging in the project.

The time period for enrolling participants in the pilot project was from January 1, 2016 to March 31, 2016. At the end of the enrollment period, the total number of patients who were willing to participate was seven. All participants were clients of the project coordinator. While the other involved prescribers informally informed the project coordinator that he or she had heard affirmative responses from "some' of their patients none, ultimately, agreed to engage in the pilot.

Sample. This was a convenience sample of seven clients. All were over 18 years old and had been prescribed long-term benzodiazepines. For the purposes of this project, long-term was defined as greater than four months.

Data Collection. Data was collected documenting the dosages of prescribed benzodiazepines for each participant at the beginning and end of this project to assess any decrease in usage. Data was collected to reflect if each participant used the web-based program during the project. Data was collected in the form of pre-project levels of anxiety using the GAD-7 at the beginning of participation in the project and at the end of participation. Additionally, the use of individual or group therapy was controlled for by collecting data regarding each participant's pre-project participation in therapy and any participation in therapy

during the project and any differences were noted. Demographic data was gathered for participants and non-participants in the project for further analysis post-project.

Instrument. The Generalized Anxiety Disorder scale-7, GAD-7, (Appendix A) was used as the measurement tool to assess levels of anxiety in participants. The GAD-7 was developed in the mid-1990s as a brief screening tool for self-assessment of anxiety symptoms. It has been in common use in behavioral health services since and has been used extensively in clinical practice as well as for study purposes (Kroenke, Spitzer, Williams & Lowe, 2007). In one large-scale study, the originators of the GAD-7 tested the instrument within a population of greater than 2700 patients. This study determined that the GAD-7 was an efficient and effective screening tool with a specificity of 82% and a sensitivity of 89% and was determined to have good reliability and procedural validity (Spitzer, Kroenke, Williams & Löwe, 2006).

Intervention. In an effort to minimize the risk of increased anxiety during this project, all participants were given written and verbal information to engage in a self-help web-based CBT program entitled "Living Life to the Full. (Appendix B.) This web-based program was developed by Dr. Chris Williams, a psychiatrist at the University of Glasgow. Each participant was also offered on-site access to a computer and one-on-one assistance to activate the program for their use.

Procedure. At entry into the project, each participant's daily dosage of benzodiazepine was recorded by the project coordinator. Each patient was administered the GAD-7 at the entry into the project to assess baseline anxiety. Each patient was provided with the verbal and written directions to access the web-based, self-help program based on cognitive-behavioral concepts ("Living Life to the Full."). Each patient's benzodiazepine dose was reduced by no more than

one-half pill within their dosage range of every month until the project was completed (i.e., if the patient's current regimen was 1 mg of clonazepam twice daily, the dosage was reduced to 0.5 mg in the morning and 1mg in the evening for a month at least, then reduced to 0.5 mg twice daily for a month, and so on.). At every med check, the prescriber monitored the client's subjective experience and if the client was actively participating on her/his own in the web-based program. At each med check the prescriber encouraged the use of web-based participation, offered support and any needed additional assistance (i.e. help via Peer Support Specialists, therapists, case managers). Once each participant's involvement in the project concluded, the GAD-7 was administered and pre- and post-project results were compared.

Stakeholders

There were numerous stakeholders involved in this project. The implementation of this project had a direct impact on prescribers' practice; each was asked to enroll clients who met inclusion criteria. The time involved in adding this component to the prescribers' already-full routine to reach potential participants was not inconsiderable. Additionally, time within scheduled sessions was needed to allow the prescribers to explain the risks of long-term benzodiazepine use and the process of weaning and its implications. Another stakeholder in this process was the patient. He or she was asked to consider alternate therapies for the treatment of anxiety symptoms, not just benzodiazepines. The changes asked of the client impacted time in session, it challenged the way the client regarded benzodiazepine dependence on his/her life, and the potentially decreased amount of time spent, overall, dealing with the mental health system having discarded the dependence on prescribers' discretionary provision of benzodiazepines.

Therapists, case managers and peer support specialists comprise another portion of stakeholders in that they were asked to assist clients in addressing their anxiety via the use of the CBT program. While none of the eventual participants engaged in the offered CBT program, these clinicians were still asked to take the time to be prepared for the possibility The business staff had a stake in this project in that there were variations in their time spent assisting clients in accessing benzodiazepine prescriptions and trouble-shooting problems with these agents.

Insurance companies and other third-party payers have a stake in this project in that they provide the means by which clients afford this care. A change in treatment that is less prescriber-dependent and allows for self-help by the patient potentially reduces the cost of health care. Families and support networks comprise another portion of the stakeholders for this project; more effective symptom treatment for the patient (their significant other) may convey limited burden to these individuals as well. A final stakeholder is the community mental health center (CMHC) itself. Reducing prescriber-dependent treatment by the implementation of a web-based, self-help program may reduce the number of visits to prescribers and thus reduce reimbursement. Conversely, for over-burdened CMHCs, this could translate into more available time for other clients with more complex and more severe mental illnesses. The CMHC may also need to change some of its policies and procedures to align with best practices in the treatment of clients with anxiety symptoms.

Responsibilities of the Team

Project coordinator (DNP Student): Designed and implemented the project; shared with other prescribers a project overview, its goals, any time limits, the intervention (web-based CBT program)—attempted to ensuring access/buy-in to program, ongoing encouragement to use

web-based program themselves and with clients. Administered GAD-7 to participants at beginning and end of project participation, collected data, served as "problem-solver" throughout project, interpreted data, ensured confidentiality and enrolled participants.

Peer Support Specialists: Remained available to assist clients in accessing computer, if needed, via on-site computer lab. They also were available to assist clients with any learning needs to ensure adequate understanding and utilization of web-site.

Therapists and Case Managers: They were made aware of clients that were in the process of tapering from benzodiazepines and provided additional support as needed to those clients.

Business Staff: Assisted in the monitoring of benzodiazepine use by accessing KASPER/INSPECT/electronic prescribing programs and forwarded this info to the project coordinator (DNP student) for data collection when requested.

Data Collection Plan and Tools

This project used two author-produced data collection. The Project Demographics chart for participants (Appendix C) was used to gather demographic data on all active participants in the project as well documentation of benzodiazepine dosage, pre- and post-project, use of the CBT web-based program and GAD-7 scores, pre- and post-project. The second tool used was the Project Demographics for non-participants (Appendix D) which gathered demographic data for those individuals opting out of the project. At the end of the project, all data from individual demographic forms was compiled through the use of the Aggregate Data- Participants form (Appendix E).

Evaluation Plan

Short-term goals:

1. All participants will successfully reduce or discontinue use of benzodiazepines by the end of the pilot project. “Successful” reduction is defined as greater than fifty percent of pre-pilot dosage.

2. All participants will demonstrate an acceptable level of distress while reducing benzodiazepine dosages throughout this pilot project as evidenced by less than a 4 point increase in GAD-7 scores from baseline scores.

3. At least 75% of participants will report participation in the web-based program by the end of the project.

Long-term Goal:

The pilot project will be converted to usual practice standards within the entire CMHC by the end of one year, bringing the agency into compliance with established best practices for the treatment of anxiety symptoms.

Evaluation

Outcome Indicator	Measure/Operational Definition	Rationale for Measure Selection	Data Collection Approach	Benchmark	Improvement Goal
Participants will successfully reduce their daily dose of benzodiazepines by the end of the pilot project (2 months.) (Short-term goal)	"Significant reduction" is defined as >50% reduction from pre-pilot daily dosage to end of pilot/dosage.	Gradual tapering (dose reduction) is preferred to abrupt withdrawal of benzodiazepines to reduce risk of withdrawal seizures, rebound symptoms, rebound hypertension and psychological distress (APA, 1990, p. 35)	Upon entry and completion of the pilot program participants' daily doses of benzodiazepines were collected from patient charts, electronic prescribing program and KASPER reports and documented on Project Demographics for Participants form.	No established benchmarks	25% decrease in overall prescribing of benzodiazepines within first 6 months of agency implementation: Number of clients prescribed benzodiazepines at end of 6 months following implementation/ number of clients prescribed benzodiazepines at beginning of 6 month implementation
Participants will report minimal increase in anxiety by end of pilot project.	"Minimal increase in anxiety" is defined as less than a 4 point increase in GAD-7 scores.	A 4-point delineation in scoring on the GAD-7 may indicate a clinically significant	Baseline GAD-7 scores will be obtained for each participant prior to beginning the weaning	No established benchmarks	Less than 4 point increase in GAD scores in clients with anxiety within the first 6 months of implementation within the agency

(Short-term goal)		change in distress—On the GAD scoring scale, changes in severity of anxiety symptoms are grouped into 4-point variations. (Spitzer, Kroenke, Williams, & Löwe, 2006.)	process; these scores will be documented on Project Demographics for Participants form. GAD-7 Scores will be obtained on each participant at the conclusion of pilot project and documented on the Project Demographics for Participants form.		
The use of a web-based CBT program ("Living Life to the Full") will minimize increased anxiety symptoms. (Short-term goal)	At least 75% of participants will report active use—defined by accessing an individual account on web-site ("Living Life to the Full") at some point during the pilot project.	CBT has consistently been shown to decrease anxiety symptoms in numerous diagnostic categories-Generalized Anxiety Disorder, Panic Disorder, PTSD, etc. (Linden, Zubragel, &	Patient use of web-based program will be documented in the patient record and collected by project coordinator (DNP student) and recorded on Project Demographics for Participants form.	No established benchmarks	25% of agency-wide client population will access web-based CBT program within first 6 months of implementation agency-wide

		Bar, 2011; Andrews, Davies, & Titov, 2011; Hendriks, Oude Voshaar, Keijsers, Hoogduin, & van Balkom,, 2008; Khoo, Dent, & Oei, 2011). Internet-based, self-help CBT programs have been shown to be as efficacious in the reduction of anxiety symptoms as face-to-face CBT therapy. (Andrews, Davies, & Titov, 2011; Titov, Andrews, Schwencke, Robinson, Peters, & Spence, 2010).			

Process Indicator	Measure/Operational Definition	Rationale for Measure Selection	Data Collection Approach	Benchmark	Improvement Goal
Education/re-education of all clinicians to accurately administer GAD-7 (Short-term goal)	Accuracy will be measured by self-report and demonstration to project coordinator (DNP student)	The questionnaires rely on patient self-report, all responses should be verified by the clinician and a definitive diagnosis made on clinical grounds, taking into account how well the patient understood the questionnaire, as well as other relevant information from the patient.	Project coordinator (DNP student) will be responsible for individual instruction and "check-off" of proficiency with each clinician.	No established benchmarks	All clinical staff will demonstrate competency in administering GAD-7 by start of agency-wide implementation
Prescribers will obtain baseline GAD-7 and GAD-7 at the completion of the project (Short-term goal)	GAD-7 is the tool selected to measure anxiety symptoms and distress to guide clinical practice during weaning process.	Withdrawal symptoms during a benzodiazepine weaning program consist primarily of increased anxiety (Ashton, 1994).	GAD-7 scores will be documented in the patient record by the prescriber and data will be collected using Project Demographics for Participants form.	No established benchmarks	80% in administering GAD-7 at baseline and at completion of pilot project, allowing for participant attrition.

Clinicians will be responsible for ensuring each participant has access to and knowledge of web-based CBT program ("Living Life to the Full") Project coordinator (DNP student) will be responsible for eliminating access barriers by providing access to computer and individual instruction if needed. (Short-term goal)	Access is defined as having a personal computer or hand-held device that can access the internet. "Knowledge of" is defined as working understanding of how the web-site works as evidenced by a return demonstration by the participant For clients who do not have access, computers and computer lab will be made available on-site. Additional support will be available via use of Peer Support Specialists to ensure adequate comfort level in accessing web.	Familiarity and adequate comfort levels in the utilization of web-based treatment programs reduces attrition [Price, Gros, McCauley, Gros, & Ruggiero, 2012).	Clinicians will document in the patient record any and all instruction, reinforcement of web-based program and identify any barriers to access for the individual participant. Project coordinator (DNP student) will be responsible for eliminating access barriers by providing access to computer and individual instruction if needed.	No established benchmarks	50% of target clients verbalize understanding of web-based program and access to the program

Prescribers will follow a consistent weaning protocol. (Short-term goal)	Weaning protocol is defined as a reduction no more than 0.5m/day per month for each participant.	Gradual tapering (dose reduction) is preferred to abrupt withdrawal of benzodiazepines to reduce risk of withdrawal seizures, rebound symptoms, rebound hypertension and psychological distress (APA, 1990, p. 35)	Dose reductions and the rationale for same will be documented in the patient record. Project coordinator will be responsible for collecting this data via patient records, e-prescribing software and KASPER reports and that data will be documented on Project Demographics for Participants form.	No established benchmarks	100% compliance with no more than 0.5mg/day dose reduction per month

Resources and Costs

Expenses

	Estimated	Actual
Site		
Facility Cost	0.0	
Salary -DNP	5000.00	
Salary -Psychiatrist	1000.00	
Salary -Peer Support Specialist	200.00	
Totals	6200.00	

	Estimated	Actual
Equipment & Supplies	0.0	
Computer Lab	0.0	
Copying Costs	100.00	
KASPER	0.0	
INSPECT	0.0	
E-prescribing System	0.0	
Totals	100.00	

	Estimated	Actual
Web-based Program		
Cost of program	0.0	
Totals	0.0	

	Estimated	Actual
Miscellaneous		
Unknown	100.00	
Totals	100.00	

	Estimated	Actual
Refreshments		
Food	100.00	
Beverages	50.00	
Totals	150.00	

	Estimated	Actual
Business Staff		
Medication Assistant	200.00	
Totals	200.00	

	Estimated	Actual
Acknowledgments		
On-the-Spot Awards	0.0	
Totals	0.0	

Demographics

Non-participants

Age

18-24 years	3%
25-34 years	16%
35-44 years	16%
45-54 years	45%
55-64 years	3%
65-74 years	16%

Gender

Male	33%
Female	67%

Marital Status

Single, Never Married	26%
Married	15%
Living with Partner	10%
Widowed	3%
Divorced	39%
Separated	3%

Ethnicity

Caucasian/White	58%
African American/Black	19%
Native American/American Indian	0
Asian/Pacific Islander	0
Other	23%

Educational Level

None	0
K-8	3%
Some High School/No Diploma	26%
High School graduate/GED	39%
Some College/No Degree	32%
Bachelor’s	.03%
Master’s	0

Employment Status

Not Working/Looking	6%
Not Working/Not Looking	81%
Part-time	6%
Full-time	6%
>1 job	0

Student

No	94%
Part-time	0
Full-time	6%

Diagnoses

Major Depression	44%
Other Anxiety Disorders	22%
Post-Traumatic Stress Disorder	19%
Bipolar I Disorder	16%
Attention Deficit Disorders	15%
Generalized Anxiety Disorder	15%
Panic Disorder	12%
Obsessive-Compulsive Disorder	1%
Bipolar II Disorder	1%
Schizophrenia	1%
Alcohol Use Disorders	1%
Traumatic Brain Injury	.03%
Intellectual Disabilities	.03%
Mood Disorder NOS	.03%
Autism Spectrum Disorders	.03%
Intermittent Explosive Disorder	.03%
Anxiolytic Dependence	.03%
Schizoaffective Disorder	.03%
Borderline Personality Disorder	.03%

Participants

Age

18-24 years	0
25-34 years	0
35-44 years	14%
45-54 years	29%

55-64 years	43%
65-74 years	0
> 75	14%

Gender

Male	29%
Female	71%

Marital Status

Single, Never Married	29%
Married	29%
Living with Partner	0
Widowed	13%
Divorced	29%
Separated	0

Ethnicity

Caucasian/White	86%
African American/Black	14%
Native American/American Indian	0
Asian/Pacific Islander	0
Other	0

Educational Level

None	0
K-8	0
Some High School/No Diploma	29%
High School graduate/GED	43%
Some College/No Degree	29%
Bachelor’s	0
Master’s	0

Employment Status

Not Working/Looking	0
Not Working/Not Looking	86%
Part-time	14%
Full-time	0
>1 job	0

Student

No	100%
Part-time	0
Full-time	0

Diagnoses

Post-Traumatic Stress Disorder	51%
Generalized Anxiety Disorder	43%
Major Depression	29%
Borderline Personality Disorder	29%
Attention Deficit Disorders	14%
Bipolar I Disorder	14%

Results

1) Goal: All participants will successfully reduce or discontinue use of benzodiazepines by the end of the pilot project. A "significant" reduction is deemed, by the project coordinator, to be at least 50%.

Participant	Beginning Benzo Dosage	Ending Benzo Dosage	% Decreased
01	3mg/day (lorazepam)	2mg/day (lorazepam)	33%
02	1mg/day (clonazepam)	0mg/day (clonazepam)	100%
03	1mg/day (clonazepam)	.75mg/day (clonazepam)	25%
04	5mg/day (diazepam)	0mg/day (diazepam)	100%
05	2.5mg/day (clonazepam)	1.5mg/day (clonazepam)	60%
06	1mg/day (clonazepam)	,5mg/day (clonazepam)	50%
07	1mg/day (clonazepam)	0mg/day (clonazepam)	100%

Result: Four out of seven participants (57%) reduced their daily benzodiazepine dosage by 50% by the end of the project. All reduced their dosages in a range of 25-100%; the total average for the sample was 66%. Of note: all but one of these participants were taking clonazepam or diazepam, both agents have relatively long half-lives, especially diazepam. Patients, who engage in a tapering program on an agent such as alprazolam, may be especially prone to subjective withdrawal symptoms or rebound anxiety due the short half-life of that particular agent.

2) Goal: All participants will demonstrate an acceptable level of distress while reducing benzodiazepine dosages throughout this pilot project as evidenced by less than a 4 point increase in GAD-7 scores from baseline scores.

Participant	GAD-7 at Beginning of project	Ranking of Score per GAD-7	GAD-7 at End of project	Ranking of Score per GAD-7	Increase/Decrease/No Change
01	17	Severe	8	Mild	Decrease
02	16	Severe	16	Severe	No Change
03	19	Severe	21	Severe	No Change
04	13	Moderate	11	Moderate	No Change
05	21	Severe	8	Mild	Decrease
06	7	Mild	8	Mild	No Change
07	19	Severe	18	Severe	No Change

Result: All demonstrated an acceptable level of distress by the end of the project. Five out of the seven (71%) demonstrated no changes in their GAD-7 scores and 2 out of the seven (28%) showed a decrease in GAD-7 scores.

3) Goal: At least 75% of participants will report participation in the web-based program by the end of the pilot project.

   Result: None of the participants used the web-based CBT program.

Control:

The project controlled for therapy.

Participant	In Therapy at Beginning of project?	In Therapy at End of project?	Change in Frequency of sessions?
01	Y	Y	N
02	Y	Y	N
03	Y	Y	N
04	N	N	n/a
05	N	N	n/a
06	N	N	n/a
07	Y	N	Y-stopped therapy

There were no changes in active therapy status for 6 of the 7 (85%) participants. One participant stopped therapy during the project. (Of note is that that participant's GAD-7 score did not change from pre- to post- project levels.)

As of August 2016, all participants in this project have remained active clients of the agency. All but one have completed their tapering programs successfully. The one remaining client is now on .5 mg clonazepam at bedtime with a goal to stop that dose at her next prescriber appointment. None of the participants have gone outside the agency for additional benzodiazepines, as evidenced by KASPER reports.

Barriers and Solutions

One anticipated barrier was a potential for lack of competency and/or comfort on the patient's part to engage in a web-based CBT program. Therefore, staff was available for rudimentary instruction and guidance in assuring that clients felt sufficiently competent in accessing the web-site. In this small sample population, no one used this tool so the resource was not needed, but for future implementation of these best practices, access to staff that is

knowledgeable and competent to assist clients with the tool as well as other CBT tools would be invaluable.

Another anticipated barrier was the reluctance of the patient to allow a reduction in benzodiazepines. While involvement in this project was voluntary, the onus was on the prescriber to provide education regarding the benefits of non-benzodiazepine treatment. Clients taking benzodiazepines are historically very reluctant to consider other forms of treatment and anticipatory anxiety increases when confronted with the possibility of "losing" the benzodiazepine.

Resistance on the part of the prescriber could have been, and likely was, in this project, a barrier. Implementing change requires varying degrees of commitment both in terms of beliefs as well as a willingness to commit the time it takes to implement change, a willingness to consider change and a buy-in to the underlying belief that what one is doing is truly best. This may or may not have been a contributor to the absence of participants in the project other than the project coordinator's clients.

Not all the prescribers who expressed interest in this project and a willingness to participate work in the same setting. Thus their proximity to the project coordinator was limited. Even if a patient invited into the project voiced some interest, these prescribers did not have immediate access to the project coordinator to enlist that patient's active involvement. Nor did the prescribers have the benefit of proximity to simply share in the day-to-day recruitment, sharing of knowledge and resources in order to enlist more active participants.

Ethical considerations. As the only participants into this project came from the Project Coordinator's caseload, it was incumbent on this prescriber to avoid coercion. Only clients for

whom this project coordinator was already tapering benzodiazepines were even invited into the project. Since the project coordinator had the "power" over prescribing these agents, it was deemed unethical to ask any client into the project who had not already consented to a tapering program months prior to the start of this pilot project.

Unintended Consequences

The project coordinator anticipated that the participants would need some intervention added to their modalities of care to lessen the risk of increased anxiety, but none of the participants engaged in this program. In spite of that, there were no increases in overall anxiety. While the addition of another tool to manage anxiety during a tapering process may indeed be helpful, the lack of use of this program did not appear to impact these specific individuals.

One patient left treatment altogether subsequent to this tapering program. It is not clear if this medication change impacted that person's decision to leave treatment as she simply dropped from care.

The use of the letter to invite clients into the project appears to have increased one person's paranoia. The letter, sent to a client not under the care of the project coordinator, prompted him to bring the letter to discuss with his prescriber asking how and to whom his medical records had been released. When she explained that his name had been provided by her as an invitation to participate in the project, he actually verbalized an initial interest but later withdrew his name from consideration, offering no reason. So, in future studies, greater care should probably be taken to alert clients that they may be invited into a project before they are even approached.

Recommendations

It is recommended that the agency engage in an ongoing practice of educating prescribers, clinicians and clients in the best practices approach to the treatment of anxiety and work diligently to limit the use of benzodiazepines, if at all, to less than a few months as recommended by the literature. This project demonstrates, in a small way, that the perceived risk of an increase in anxiety once these agents are reduced and/or eliminated may not necessarily have a basis in fact or real experience.

Group support has long been a staple of mental health services. The agency should consider developing groups for people with anxiety that are in various stages of benzodiazepine dependence to provide peer support through the process.

Changing a culture is time and energy intensive. Therefore, the staff need the support of the agency to allow these prescribers and staff to take the time needed to educate clients on the benefits of eliminating these agents and to provide additional tools and resources such as extended time with prescribers and more opportunities for individual and group therapies to support clients as they learn to manage their anxiety without the use of benzodiazepines. On possible solution to this may be the use of two-step appointments wherein the patient's appointment with the therapist would precede the prescriber appointment. This would afford the patient the time and opportunity to work with a clinician on individual CBT or enable the patient time with the clinician to engage with a web-based CBT program and reinforce skills for self-use.

During the time this project was conceived, developed, and implemented, this agency began to work on a benzodiazepine cessation policy and procedure. The project coordinator was consulted periodically, regarding the progress and outcome of this project. The medical director

and assistant medical director consulted with the project coordinator throughout that planning process. On July 1, 2016, the agency adopted a policy that it would become benzodiazepine free and would begin tapering all benzodiazepines within the year. The policy also requires that no new prescriptions for benzodiazepines will be started by its prescribers after July 1, 2016. The implementation of this policy, to date, appears to be going smoothly with minimal disruption to clients'' overall anxiety levels.

Required Approvals

Approvals were obtained from the Institutional Review Boards (IRB) of both Bellarmine University and Seven Counties Services before this pilot project was implemented. The Bellarmine University IRB is on file in the office of the Department Chair for the Doctorate in Nursing Practice Program, Dr. Sherrill Cronin. The IRB approval letter can be found in Appendix F.

References

American Academy of Pain Management (2013). Prescriptions for benzodiazepines rising and risky when combined with opioids, Stanford researchers warn. *American Academy of Pain Management.* Retrieved from http//www.painmed.org

American Psychiatric Association. (1990). *Benzodiazepine dependence, toxicity and abuse: A task force report of the American Psychiatric Association.* Washington, DC.

Andrews, G., Davies, M., & Titov, N. (2011). Effectiveness randomized controlled trial of face to face versus Internet cognitive behaviour therapy for social phobia. *Australian and New Zealand Journal of Psychiatry, 45*(4), 337-340. doi: 10.3109/00048674.2010.538840

Anthony, W. (1993). Recovery from mental illness: The guiding vision of the mental health service system in the 1990s. *Psychosocial Rehabilitation Journal, 16(4),* 11-23.

Ashton, C. (1994). Guidelines for the rational use of benzodiazepines, when and what to use. *The Ashton Manual.* http://www.benzo.org.uk/asgr.htm

Bachhuber, M., Hennessy, S., Cunningham, C., & Starrels, J. (2016). Increasing benzodiazepine prescriptions and overdose mortality in the United States, 1996–2013. *The American Journal of Public Health, 106*(4), 686-688.

Cascade, E. & Kalali, A. (2008). Use of benzodiazepines in the treatment of anxiety. *Innovations in Clinical Neuroscience, 5*(9), 21–22. Retrieved from http://innovationscns.com/use-of-benzodiazepines-in-the-treatment-of-anxiety

Centers for Disease Control (2011). Prescription painkiller overdoses. Centers for Disease Control. Retrieved from http//www.cdc.gov/homeandrecreationalsafety/rxbrief

Cohron, P. (2014). The Commonwealth's response to Kentucky's pill mill problem. *Kentucky Law Journal Online, 102,* 1-7.

Cunningham, C. M., Hanley, G. E., & Morgan, S. (2010). Patterns in the use of benzodiazepines in British Columbia: examining the impact of increasing research and guideline cautions against long-term use. *Health Policy, 97*(23),

122-129.

de Gage, S., Bégaud, B., Bazin, F., Verdoux, H., Dartigues, J., Pérès, K., Kurth, T., & Pariente, A. (2012). Benzodiazepine use and risk of dementia: prospective population based study. *British Medical Journal, 345*, 1-12. doi: 10.1136/bmj.e6231

Dormuth, C., Miller, T., Huang, A., Mamdani., M. & Juurlink, D. (2012). Effect of a centralized prescription network on inappropriate prescriptions for opioid analgesics and benzodiazepines. *Canadian Medical Journal Association*, *184*(16), E852-E856.

Frese, F. J., III, Stanley, J., Kress, K., & Vogel-Scibilia, S. (2001). Integrating evidence based practices and the recovery model. *Psychiatric Services, 52*(11), 1462-1468.

Gosselin, P., Ladouceur, R., Morin, C. M., Dugas, M. J., & Baillargeon, L. (2006). Benzodiazepine discontinuation among adults with GAD: A randomized trial of cognitive-behavioral therapy. *Journal of Consulting and Clinical Psychology, 74*(5), 908-919.

Hendriks, G. J., Oude Voshaar, R. C., Keijsers, G. P., Hoogduin, C. A., & van Balkom, A. J. (2008). Cognitive-behavioural therapy for late-life anxiety disorders: A systematic review and meta-analysis, *Acta Psychiatrica Scandinavia*. *117*(6), 403- 411. doi: 10.1111/j.1600-0447.2008.01190.x.

Khoo, A., Dent, M. T., & Oei, T. P. (2011). Group cognitive behaviour therapy for military service-related post-traumatic stress disorder: effectiveness, sustainability and repeatability. *Australian and New Zealand Journal of Psychiatry*, *45*(8), 663-672. doi: 10.3109/00048674.2011.590464

Kroenke, K., Spitzer, R., Williams, J., Monahan, P. and Lowe, B. (2007). Anxiety disorders in primary care: prevalence, impairment, comorbidity, and detection. *Annals of Internal Medicine*, *146*(5), 317-325. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/17339617

Linden, M., Zubragel, D., & Bar, T. (2011). Occupational functioning, sickness absence and medication utilization before and after cognitive-behaviour therapy for generalized anxiety disorders. *Clinical Psychology and Psychotherapy*, *18*(3), 218-224. doi: 10.1002/cpp.712

Magellan Health Services. (2012). Magellan clinical practice guideline for the assessment and treatment of generalized anxiety disorder in adults. Retrieved from https://www.magellanprovider.com/mhs/mgl/providing_care/clinical_guidelines/clin_prac_guidelines/gad.pdf

NICE: National Collaborating Centre for Mental Health, National Collaborating Centre for Primary Care (2011). Generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults. Management in primary, secondary and community care. London (UK): *National Institute for Health and Clinical Excellence.* (Clinical guideline no.113). Retrieved from http://www.guideline.gov

Olfson, M. & Pincus, H.A. (1994). Use of benzodiazepines in the community. *Archives of Internal Medicine, 154*(11), 1235-1240. doi: 10.1001/archinte.1994.00420110079009

Parton, E. (2012). Prescribing controlled substances. *Kentucky Coalition of Nurse Practitioners and Nurse Midwives Legislative Task Force*. Retrieved from http://www.kcnpnm.org/?RX_Guide

Price, M., Gros, D. F., McCauley, J. L., Gros, K. S., & Ruggiero, K. J. (2012). Nonuse and dropout attrition for a web-based mental health intervention delivered in a post-disaster context. *Psychiatry*, *75*(3), 267-284. doi: 10.1521/psyc.2012.75.3.267

Sanyal, C., Asbridge, M., Kisely, S., Sketris, I., & Andreou, P. (2011). The utilization of antidepressants and benzodiazepines among people with major depression in Canada. *Canadian Journal of Psychiatry*, *56*(11), 667-676.

Smith, A. J., & Tett, S. E. (2010). Improving the use of benzodiazepines--is it possible? A non-systematic review of interventions tried in the last 20 years. *BMC Health Services Research*, 10: 321. doi: 10.1186/1472-6963-10-321

Spitzer, R. L., Kroenke, K., Williams, J. B. W., & Löwe, B. (2006). A brief measure for assessing generalized anxiety disorder: The GAD-7. *Archives of Internal Medicine, 166*(10), 1092-2010

Substance Abuse and Mental health Administration. (2013). *Behavioral health, United States,*

2012 (HHS Publication No. SMA 13-4797). Rockville, MD: Substance Abuse and Mental Health Services Administration.

Svetla, S., Bunn, T. & Lambert, J. (2014). Drug overdose deaths, hospitalizations, and emergency department visits. *Kentucky Injury Prevention and Research Center*. Retrieved from http://www.mc.uky.edu/kiprc/PDF/Drug-Overdose-report

Titov, N., Andrews, G., Schwencke, G., Robinson, E., Peters, L., & Spence, J. (2010). Randomized controlled trial of Internet cognitive behavioural treatment for social phobia with and without motivational enhancement strategies. *Australian and New Zealand Journal of Psychiatry*, 44(10), 938-945. doi: 10.3109/00048674.2010.493859

Trust for America's Health. (2013, October 7). Kentucky has the third highest drug overdose mortality rate in the United States. Trust for America's Health. Retrieved from http://healthyamericans.org/reports/drugabuse2013

Appendix A

GAD-7

GAD-7

Identifier | Date

Please read each statement and record a number 0, 1, 2 or 3 which indicates how much the statement applied to you over the past two weeks. There are no right or wrong answers. Do not spend too much time on any one statement. This assessment is not intended to be a diagnosis. If you are concerned about your results in any way, please speak with a qualified health professional.

0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day

1	Feeling nervous, anxious or on edge	
2	Not being able to stop or control worrying	
3	Worrying too much about different things	
4	Trouble relaxing	
5	Being so restless that it is hard to sit still	
6	Becoming easily annoyed or irritable	
7	Feeling afraid as if something awful might happen	

Total GAD-7 score =

Privacy - please note - this form neither saves nor transmits any information about you or your assessment scores. If you wish to keep your results you will need to print this document. These results are intended as a guide to your health and are presented for educational purposes only. They are not intended to be a clinical diagnosis. If you are concerned in any way about your health, please consult with a qualified health professional.

Serenity Programme™ - www.serene.me.uk - GAD-7 (print version)

Scoring guide

Normal	Mild	Moderate	Severe
0 - 4	5 - 9	10 - 14	15 - 21

The maximum score of the GAD-7 is 21, lower scores are better. Scores are assigned in the following manner:

0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day

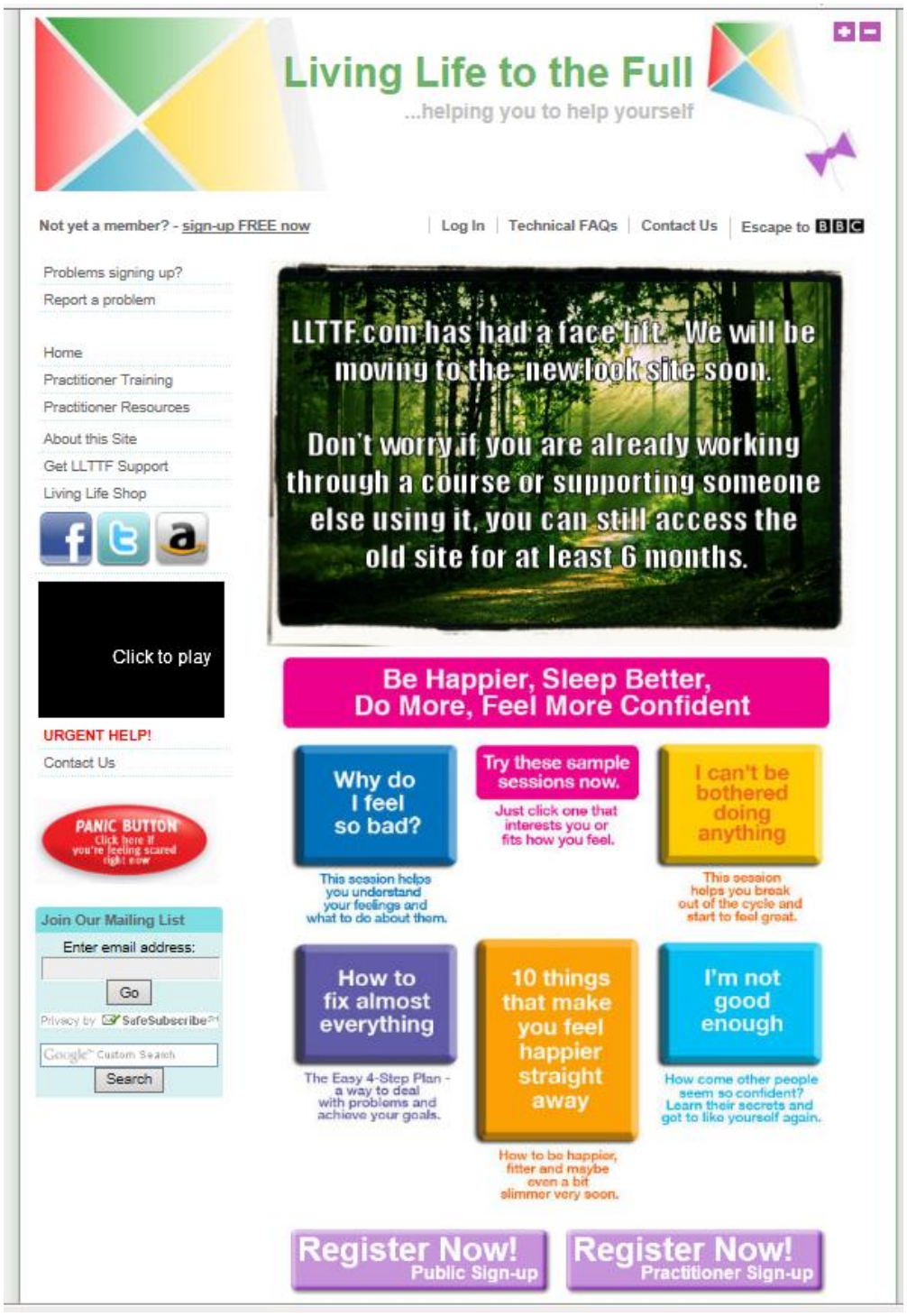
The total score is simply the sum of question items one through seven. Scores of 5, 10 and 15 are taken as the cut off points for mild, moderate, and severe anxiety respectively. When used as a screening tool, further evaluation is recommended should the score be ten or greater.

Kroenke, K., Spitzer, R.L., Williams, J.B. *et al;* Anxiety disorders in primary care: Prevalence, impairment, comorbidity, and detection. Ann Intern Med. 2007 Mar 6; 146(5):317-25

Spitzer, R.L, Kroenke, K. & Williams, J.B. *et al.* A brief measure for assessing generalised anxiety disorder: the GAD-7. *Arch. Intern. Med.* 2006: 166:1092-7.

Appendix B

Living Life to the Fullest Web-site



Appendix C

Project Demographics Master Data Collection Tool-Participants

Study Participant Number	Name	MR #	Prescriber				
Age	18-24	25-34	35-44	45-54	55-64	65-74	>75
Gender	M	F					
Marital Status	Single, never married	Married	Living with Partner	Widowed	Divorced	Separated	
Ethnicity	Caucasian /Whites	African American/Black	Native American/ American Indian	Asian/ Pacific Islander	Other		

Educational Level	None	K-8	Some HS/no diploma	HS grad/GED	Some college/no degree
Associates	Bachelors			Masters	
Employment Status	Not working/looking	Not working/not looking	Part-time	Full-time	>1 job
Student	No	Part-time	Full-time		

Diagnoses	GAD	OCD	PTSD	Panic D/O	Other anxiety
Other (list)	Other (list)			Other (list)	
Other (list)	Other (list)			Other (list)	
Other (list)				Other (list)	
Other (list)	Other (list)			Other (list)	

Beginning dose (drug)	Ending dose (drug)	GAD at beginning of study	Ranking of GAD score (mild, mod, severe)	GAD at end of study	Ranking of GAD score (mild, mod, severe)	In therapy at beginning of study (Y/N)	In therapy at end of	Use of web-based CBT during study

Appendix D

Project Demographics Master Data Collection Tool- Non-participants

Study Participant Number	Name	MR #	Prescriber				
Age	18-24	25-34	35-44	45-54	55-64	65-74	>75
Gender	M	F					
Marital Status	Single, never married	Married	Living with Partner	Widowed	Divorced	Separated	
Ethnicity	Caucasian /Whites	African American/Black	Native American/ American Indian	Asian/ Pacific Islander	Other		

Educational Level	None	K-8	Some HS/no diploma	HS grad/GED	Some college/no degree
Associates	Bachelors			Masters	
Employment Status	Not working/looking	Not working/not looking	Part-time	Full-time	>1 job
Student	No	Part-time	Full-time		

Diagnoses	GAD	OCD	PTSD	Panic D/O	Other anxiety
Other (list)	Other (list)			Other (list)	
Other (list)	Other (list)			Other (list)	
Other (list)				Other (list)	
Other (list)	Other (list)			Other (list)	

Appendix E

Aggregate Data- Participants

Participant	Beginning dose benzo	Ending dose benzo	% decreased	GAD at beginning of project	Ranking of Score per GAD	GAD at end of project	Ranking of Score per GAD	+/-+no change

Participants	Change in score =/-	In thx at beginning of project?	In thx at end of project?	Change in frequency of sessions?

Appendix F

Required Approval

Seven Counties Services, Inc.
www.sevencounties.org

For appointments
call 589-1100
or 1-800-264-8799
TDD–589-4259
or 1-877-589-4259

Behavioral Health
9702 Stonestreet Rd.
Suite 110
Louisville KY 40272
502-589-8920
FAX 502-447-1967

2225 West Broadway
Louisville KY 40211-1087
502-589-8910
FAX 502-772-2084

School-Based Services
4710 Champions Trace
Suite 107
Louisville KY 40218
502-454-6343
FAX 502-459-9209

Brief Treatment Unit
4710 Champions Trace
Suite 107
Louisville KY 40218
502-454-6343
FAX 502-459-9209

June 26, 2015

Gayle Mink, MSN APRN
Seven Counties Services, Inc.

Dear Gayle,

Congratulations, the IRB of Seven Counties Services, Inc., has approved your research proposal entitled:

Reducing the Long-term Benzodiazepines Use in the Treatment of Anxiety

Thank you for the additional information you provided. You are authorized to conduct your research through 6/26/2016. If you need additional time, please let the committee know.

One of our reviewers did say there were some typo's in the consent and asked that you correct them and send us a clean copy. (i.e., on second page under Procedures and Protocol you reference the "7-quesiotn" screening tool.) Otherwise, all safeguards are met and you are free to proceed.

Attached, please find our general Agreement, obtained from all researchers who conduct their investigations at Seven Counties Services, Inc. The Agreement simply acknowledges that you will abide by the terms of your proposal, submit any revisions to the IRB in a timely manner, and provide the IRB with a summary of your results upon completion of your research.

We wish you well in your investigation. Please feel free to contact the IRB if you have any questions regarding your project.

Sincerely,

Ron Van Treuren, Ph.D.
Chair, IRB Seven Counties Services, Inc.
rvantreu@sevencounties.org

APPROVED
JUN 26 2015
Seven Counties Services, Inc.
I.R.B.

Providing behavioral health, chemical dependency, and developmental disabilities planning and services for Bullitt, Henry, Jefferson, Oldham, Shelby, Spencer and Trimble counties.