

CONSENT TO PARTICIPATE IN RESEARCH

Mental Illness and Wellness Study

The Effectiveness of Guided Self-Help Administered, Comprehensive Interventions in the Prevention and Treatment of Mental Illness and the Enhancement of Mental Wellness

Science and Public Policy Institute
Comparative Effectiveness Research Program
Washington, D.C.

July 2010

INVITATION TO PARTICIPATE

You are invited to participate in a research study of the effectiveness of guided self-help administered, sequenced, custom interventions for the enhancement of mental wellness. A primary goal of this research is to gather scientific data that can be used as evidence to support health insurance coverage for interventions aimed at mental illnesses that are influenced adversely by a range of environmental and personal lifestyle conditions.

You have been invited to participate in this study because:

- You suffer from one of the following mental health conditions which may derive from or be significantly effected by environmentally induced cell-membrane damage: Anxiety Disorder, Depression, Bipolar Disorder, Mood Disorder, Substance Use Disorder, Eating Disorder, or Post-Traumatic Stress Disorder;
- You have been diagnosed with another mental health illness or an environmental illness not listed above;
- You are the parent of a young person who suffers from one of the mental health illness conditions mentioned above;
- You have expressed an interest in following healthful adaptation protocols as a means for prevention and/or recovery from a mental health disorder;
- You have expressed an interest in following healthful adaptation protocols as a means for enhancing your mental wellness.

This work is being conducted under the auspices of the non-profit Science and Public Policy Institute, Comparative Effectiveness Research Program, based in Washington, D.C.¹ The Principal Investigator for this study is Dr. George L. Carlo.²

¹ *The Science and Public Policy Institute (SPPI) was established in 1989 in Washington, D.C.. The mission of SPPI is to provide guidance to government agencies and the public on complex issues where science can be applied to assist in making informed public health, public policy and individual health protection decisions. SPPI has provided guidance on myriad issues including occupational health hazards, environmental and ecological damage, Agent Orange, abandoned hazardous waste sites, antiviral treatments, food safety, smoking cessation, indoor air quality standards, silicone breast implants, electromagnetic field exposures, clinical research criteria, and nanotechnology. Note that the Science and Public Policy Institute name has been used by other political entities located in states outside of the District of Columbia. SPPI is not affiliated with any of those entities.*

² *Dr. George Carlo is Chairman of the nonprofit Science and Public Policy Institute based in Washington, D.C. (8666204459), a position he has held since 1989. Over the past thirty years, he has been at the forefront of researching and developing strategies for managing environmental illness. He was among the first scientists on the scene at the infamous Love Canal chemical crisis in Niagara Falls, New York in 1978 that lead to the Superfund law addressing hazards from abandoned hazardous waste sites. He was integral in writing the enabling legislation that established the Agency for Toxic Substances and Disease Registry within the Department of Health and Human Services, a primary group addressing the effects of environmental contaminants. He served for ten years on the U.S. Congress' Office of Technology Assessment Agent Orange Advisory Panel, providing advice to Viet Nam Veteran's suffering from the effects of the dioxin laced defoliant program. During the 1990s, he headed Wireless Technology Research, the world's largest program to date addressing the health impacts of wireless technology related electromagnetic radiation. Among his more than 200 peer-reviewed publications are papers addressing environmentally caused reproductive effects, infertility, tumors, cancer, electrosensitivity, autism, and multiple chemical sensitivities. He has training in pathology, epidemiology, medical science and law, and over the past thirty years has served on the medical and research faculties of the State University of New York at Buffalo, the University of Arkansas and the George Washington University.*

Research Assistants and study 'Guides' who will be identified to you by name through the course of the study as you encounter them, will carry out all major tasks in the work. The study design has been reviewed and approved by the SPPI internal Institutional Review Board.

The study will enlist participants beginning June 15, 2010 with open enrollment through at least December 31, 2012. The first analysis will be done at that time and the final report will be completed within four months following. A summary of the report will be made available to participants upon request.

Your participation in this study is entirely voluntary.

It is anticipated that benefits derived from the services received through the course of the study will be variable from participant to participant. Benefits to society of this research include the provision of data that will enhance the possibility of insurance coverage for the comprehensive interventions applied to the illnesses and conditions within the scope of the study as well as lay groundwork for coverage for other interventions aimed at preventing, treating and otherwise managing environmental and mental illness.

Please read the information contained herein carefully, and ask questions about anything you do not understand before deciding whether or not to participate. Contact information for such queries is presented on page 17 of this document.

CONTEXTUAL BACKGROUND FOR THIS STUDY

Mental illness and wellness are part of a continuum that involves cognitive and non-cognitive processes as well as sympathetic and parasympathetic nervous system function. In short, this means that mental health and wellness have both mental and physical attributes irreversibly connected. Traditional western medical approaches to treating mental illnesses have focused on the mental aspect primarily, with the physical aspects addressed through pharmacological medication.

The underlying assumption has traditionally been that the mental aspects of these conditions drive the physical aspects. Science now shows that in many cases, the physical aspects drive the mental aspects, with overuse of medication making the conditions worse instead of better. Because it is often difficult to know which aspect, physical or mental, is most predominant in causing the clinical conditions of mental illness, it is necessary to use all the tools available for treatment to be most assured of successful outcomes. This holds true for prevention and treatment of mental illness as well as enhancement of mental wellness.

Non-traditional approaches to addressing mental disorders have not become mainstream in the United States and many of these approaches are not covered by health insurance. As such, these integrative or comprehensive remedies, which can be of profound positivity to many, are not available to the population at large but only to those with means to afford all types of intervention. This study is aimed at documenting the usefulness of the most comprehensive approaches to mental illness and wellness, with the intention of providing grounding for use of the full range of helpful tools by the population at large.

SCOPE OF THE MENTAL ILLNESS PROBLEM

Mental health conditions are very common in the United States with one in four adults suffering from what can be classified a mental disorder during any given year.

U.S. Adults with a Mental Disorder in Any Year³

Type of Mental Disorder	% Adults
Anxiety disorder	18.1
Major depressive disorder	6.7
Substance use disorder	3.8
Bipolar disorder	2.6
Eating disorders	2.1
Schizophrenia	1.1
Any mental disorder	26.2

Mental illnesses can be mild, moderate, or severe. About 6% of adults (1 in 17) suffer from a serious mental illness, reporting an average of 88 days (approximately 3 months) during the past year when they were too ill to carry out their normal daily activities.

Mental disorders often start in adolescence or early adulthood. When they start at this age, they can affect the young person's education, moving into adult occupational roles, forming key relationships and the establishment of healthy life-long habits. Consequently, mental disorders can cause disability across a person's lifespan.

Medical experts consider mental disorders among the most disabling illnesses. However, because disability caused by mental disorders may not be visible to others, people with mental disorders can be negatively judged as being weak, lazy, uncooperative, or not really ill. This lack of understanding contributes to the stigma that people with mental disorders are irreparably dysfunctional. It helps to understand the degree of disability that mental disorders can cause by comparing it to physical illnesses. For example:⁴

- The disability from moderate depression is similar to the impact from relapsing multiple sclerosis, severe asthma, or chronic Hepatitis B.

³ Kessler, R.C., Chiu, W.T., Demier, O., and Walters, E.E. (2005) "Prevalence, severity, and comorbidity of twelve month DSM-IV disorders in the National Comorbidity Survey Replication (NDS-R). *Archives of General Psychiatry*, 62, 617-67

⁴ "Disability" refers to the amount of disruption a health problem causes to a person's ability to:

- Work
- Carry out daily activities
- Engage in satisfying relationships

- The disability from severe post-traumatic stress disorder is comparable to the disability from paraplegia.⁵

Suicide represents the most severe of mental illness symptoms. Approximately one million people in the world die by suicide each year. This represents a "global" mortality rate of 16 per 100,000, or one death every 40 seconds. In the past 45 years, suicide rates have increased by 60% worldwide. Suicide is now among the three leading causes of death among those aged 15-44 years (both sexes); these figures do not include suicide attempts, which are up to 20 times more frequent than completed suicide.⁶

According to the American Association of Suicidology (AAS), an organization which promotes research, public awareness programs, public education and training for professionals and volunteers, and serves as a national clearinghouse for information on suicide:

- More than 33,000 people in the United States die by suicide every year.
- In 2007 (latest available data), there were 34,598 reported suicide deaths.
- 2007 showed more than a 3% increase in rate from 2006 and runs counter to what has been a rather long trend of decreases or steady rates. Youth showed a decline, but many other groups showed slight increases. The most noticeable change has been an increase in the middle adult years, with the rates for 45-54 in particular exceeding that for the elderly (and being the highest rate by age).
- Currently, suicide is the 11th leading cause of death in the United States.
- A person dies by suicide every 15 minutes in the United States. A suicide attempt is estimated to be made once every 29 seconds (approximately 1.1 million attempts each year).
- Ninety percent of all people who die by suicide have a diagnosable psychiatric disorder at the time of their death.
- There are 3.6 male suicides for every female suicide, and three times as many females as males attempt suicide.
- Every day, approximately 95 Americans take their own life, and over 2,800 more attempt to do so.⁷

Untreated Depression is The Number One Cause for Suicide

More than 90 percent of people who die by suicide have a mental illness at the time of their death. The most common mental illness is depression. Untreated mental illness (including depression, bipolar disorder, schizophrenia, eating disorders, and others) is part of the cause for the vast majority of suicides. Also, some people are genetically predisposed to depression, and thus they may not appear to be undergoing any negative life experiences, yet still become depressed and end their own lives.

- Over 60% of all people who die by suicide suffer from major depression. If one includes alcoholics who are depressed, this figure rises to over 75%.

⁵ Stouthard, M.E.A., Essink-Bot, M.L., Bonsel, F.J. et al. (1997) *Disability weights for diseases in the Netherlands*. Erasmus University, Rotterdam.

⁶ World Health Organization: http://www.who.int/mental_health/prevention/suicide/suicideprevent/en/index.html

⁷ American Association of Suicidology: <http://www.suicidology.org/web/guest/stats-and-tools/statistics>

- Depression affects nearly 10% of Americans ages 18 and over in a given year – or more than 24 million people.
- More Americans suffer from depression than coronary heart disease (17 million), cancer (12 million), and HIV/AIDS (1 million).

About 15% of the population will suffer from clinical depression at some time during their lifetime. Thirty percent of all clinically depressed patients attempt suicide; half of them ultimately die by suicide. Depression is among the most treatable of psychiatric illnesses. Between 80% and 90% of people with depression respond positively to treatment, and almost all patients gain some relief from their symptoms. But first, depression has to be recognized.⁸

Elderly Males and Young People Are High Risk Groups

Traditionally, suicide rates have been highest among elderly males, but they also rank high among young people. These rates have been increasing to such an extent that young people are now the group at the highest risk in one-third of the world's countries – both developed and developing countries.⁹ In 2007, the most noticeable change was an increase in the middle adult years, with the rates for 45-54 in particular exceeding that for the elderly (and being the highest rate by age).

General Social Disorders As Causes

Mental illness conditions (particularly depression and substance abuse) are associated with more than 90% of all cases of suicide. However, suicide can result from many complex socio-cultural factors and is more likely to occur during periods of socioeconomic, family, and individual crisis situations (e.g., loss of a loved one, unemployment, honor, etc.).¹⁰

Post-Traumatic Stress

In 2004, the United States Army published its first study on the mental health of troops (Army and Marine combat units) who fought in Iraq or Afghanistan. They surveyed over 6000 soldiers at four different times in their deployment and return home and found that about one in eight reported symptoms of post-traumatic stress disorder. This study showed that less than half of those with problems sought help, mostly due to the fear of being stigmatized or the possibility it might hurt their career.¹¹

Military Personnel, Veterans and Their Families

"The Real Warriors Campaign" is sponsored by the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury (DCoE). The campaign is designed to help servicemembers overcome the stigma associated with seeking psychological help and encourage servicemembers to seek out help when they need it. The "Real Warriors Campaign" uses social networking, radio, television, posters, flyers, and a Web site to reach active-duty servicemembers,

⁸ American Foundation for Suicide Prevention:

http://www.afsp.org/index.cfm?fuseaction=home.viewpage&page_id=050FEA9F-B064-4092-B1135C3A70DE1FDA

⁹ World Health Organization: http://www.who.int/mental_health/prevention/suicide/suicideprevent/en/index.html

¹⁰ World Health Organization: http://www.who.int/mental_health/prevention/suicide/suicideprevent/en/

¹¹ MSNBC: <http://www.msnbc.msn.com/id/5334479/>

military veterans, members of the National Guard and the Reserves, as well as family members and health professionals. The campaign features stories of real service members who have sought treatment and are continuing to serve¹²

Psychological Stress and Substance Use Disorder Among Veterans

Combined data from SAMHSA's 2004 - 2006 National Surveys on Drug Use and Health indicate that an annual average of 7% of veterans aged 18 or older experienced past year serious psychological distress, 7.1% met the criteria for a past year substance use disorder, and 1.5% had co-occurring serious psychological distress and substance use disorder. Veterans aged 18 to 25 were more likely than older veterans to have higher rates of serious psychological distress, substance use disorder, or co-occurring psychological distress and substance use disorder in the past year. Veterans with family incomes of less than \$20,000 per year were more likely than veterans with higher family incomes to have had serious psychological distress, substance use disorder, or co-occurring psychological distress and substance use disorder in the past year.¹³

Suicide Survivors Are A High Risk Group

The National Center for Health Statistics conservatively estimates that each suicide death impacts six individuals. In the United States, that represents more than 198,000 individuals each year, based on 33,000+ suicide deaths annually.

Enhancing Mental Wellness

The good news is that with proper early and comprehensive intervention, mental illness is imminently treatable for nearly all cases. According to a national survey by the Substance Abuse and Mental Health Services Administration (SAMHSA) there are an estimated 9.8 million adults aged 18 or older living with serious mental illness. Among adults, the prevalence of serious mental illness is highest in the 18 to 25 year age group, yet this age group is also the least likely to receive services or counseling for mental health issues.¹⁴ Thus, a major challenge is increasing awareness regarding hopeful intervention successes and removing the stigma associated with the erroneous belief that mental illness is a life-long curse.

Each individual is unique and therefore uniquely approaches their mental health. Not many people have even the most basic knowledge of what the signs and symptoms of a developing mental health condition are, let alone how to deal with a mental health crisis situation. Lack of knowledge, or not knowing what to do or say, causes fear. Fear perpetuates the stigma associated with mental health conditions. Education ends discrimination.

In 2003, the final report of the President's New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America*, called for recovery to be the "common, recognized outcome of mental health services." In this report, recovery was defined as

¹² Army Behavioral Health: <http://www.behavioralhealth.army.mil/ptsd/index.html>

¹³ National Survey on Drug Use and Health Nov 2007 report:
<http://www.oas.samhsa.gov/2k7/veteransDual/veteransDual.htm>

¹⁴ Substance Abuse and Mental Health Services Administration
<http://www.samhsa.gov/newsroom/advisories/1005252813.aspx>

“the process in which people are able to live, work, learn, and participate fully in their communities.”¹⁵ Recovery is a personal journey with the goals of hope, empowerment, and autonomy. Too many Americans are unaware that mental disorders can be treated and recovery is possible.

PURPOSE OF THIS STUDY

The purpose of this study is to apply the most comprehensive protocols available that address simultaneously the mental and physical components of mental illness, and to document their usefulness. Specifically, the study:

- Promotes recovery
- Educates participants about environmental factors
- Initiates a guided self-help process, customized to the needs of the individual

STUDY PROCEDURES

This study focuses primarily on the minimal direction, guided self-help system for delivering interventions customized to the needs of each individual participant. Each participant will be lead through the study process over the subsequent months by a ‘guide’ who will serve mainly in the capacity of a coach. The ‘guides’ are charged with helping the participant through the identified intervention pathway by providing choices for the participant and will endeavor to offer minimal direction.

One purpose of the study is to identify minimal needs for direct interaction between a ‘guide’ and the participant so that the most resource-efficient procedures can be identified in the study. Prior to enrollment in the study, and then during the process of the study itself, eligibility evaluations will be made for each participant to determine whether or not there is a high probability that the guided self-help approach will be successful for the individual participant. In cases where either the initial evaluation or later evaluations suggest that guided self-help is not likely to glean favorable outcomes for the participant, the participant will be offered two choices:

- The opportunity to identify a clinician with whom they would like to work and having the delivery of the interventions coordinated through that clinician.¹⁶
- The opportunity to be placed on a study list for one of the subsequent studies planned using other delivery systems for the protocol pathways, website based or clinical center based.

For those that volunteer to participate in this study and are determined to be eligible, they will be asked to do the following things:

- Complete evaluation questionnaires at the beginning of the study under the supervision of a ‘study guide’. A ‘study guide’ is the member of the research team responsible for seeing you

¹⁵ New Freedom Commission on Mental Health (DHHS Pub. No. SMA-03-3832) <http://www.mentalhealthcommission.gov>

¹⁶ Because there are potential health benefits associated with participation, it is the policy of SPPI to not deny those opportunities for wellness to anyone. Study personnel will provide recommendations of clinicians and will also work with new clinicians interested in the subject matter. The costs of these, as the others involved in the study, will be borne jointly by SPPI (professional services) and the participant (interventions).

through the study processes over the length of the study. The primary function of the 'guide' is to lead you through the process that has been defined as the protocol for this study. 'Guides' are not medical personnel and will not be able to provide recommendations. They will provide choices for you, the participant, to decide upon.

- Use your best efforts to follow intervention protocol pathways that derive from the questionnaires that you will complete through the study. Your 'guide' will contact you monthly to provide updates on your intervention pathway choices and progress. You can contact your 'guide' at your need.
- Pay for the services that are administered to you through the study to the best of your ability.¹⁷
- Participate to the best of your ability in discussing and choosing specific interventions that are defined in your intervention protocols
- Complete evaluation questionnaires during the study and at the end of the study, explaining the things in the study that worked best and those that did not.
- Complete evaluation questionnaires during the study and at the end of the study, explaining your progress or lack of progress toward feeling better.

The protocols being studied are customized for every individual, based on their own unique situation. There is no generic protocol. The fundamental premise of the approach is to place the study participant in the best position to adapt healthfully to the changing environment so that adverse effects are minimized and wellness is maximized in both the short-term and long-term. More detailed scientific information appears in the Appendix beginning on page 15.

The methods employed include activation of both genetic and epigenetic adaptive mechanisms through specifically designed and customized protocols for each individual.

A six-phased protocol is designed for each participant that encompasses an 18-month period.

- Phase 1: Neurological re-balancing to reduce external and internal sources of oxidative stress. This is necessary because if the neurological/energetic systems are not balanced, there is limited biological access to individual cells and tissues where the adaptive mechanisms occur, and very limited capacity for the person to achieve healthful adaptation.
- Phase 2: Cellular energy enhancement and first line oxidation mitigation through specific-function nutraceuticals.
- Phase 3: Cell membrane opening and adaptation facilitation, primarily through the use of specific-function nutraceuticals.
- Phase 4: Detoxification of spaces between cells, where necessary, via specific-function nutraceuticals.
- Phase 5: Intracellular detoxification, where necessary, via specific function nutraceuticals.
- Phase 6: Maintenance

¹⁷ Choices with respect to which interventions are employed are left to the participant. Thus, the participant is integrally involved in determining the course of care and the cost of care, which is a reality for most people as they seek out all types of health care. The analyses at the end of the study will address personal financial means as variables determinative of favorable and unfavorable health outcomes.

The design of this study is descriptive in nature, meaning that specific null hypotheses defined *a priori* are not being employed. Specific null hypotheses for testing will be defined *a posteriori* based on the extent and the nature of the data gathered. Thus, participants in this study will not be defined to treatment and control groups ahead of time. There are no placebos being used in the research. Each participant will be afforded the opportunity to glean the full range of benefits encompassed within the intervention protocols being employed. The study endeavors to define the most likely successful protocol pathway for each participant and comparisons will be made between groups of people who self-select by virtue of the intervention choices they make throughout the research study. Participants will be thus placed into different protocol content groups for statistical analysis.¹⁸

There is no manipulation of protocols for the benefit of the study at the expense of participants.

POTENTIAL RISKS AND DISCOMFORTS

The study is designed to empower choices among participants from recommended protocol pathways based on questionnaires and in some cases, laboratory tests, administered throughout the study. Each participant is, in effect, under his or her own care by design of the study and therefore has control over determining comfort levels with each intervention, including cost.

Intervention choices in the study will be integrative and customized to the participant, based on iterative queries including Medical Risk Assessments and Intervention Pathway Evaluations. These customized integrative choices include:

- Neurological re-balancing tools such as acupuncture, massage, chiropractic, yoga, meditation, prayer and other energy medicine techniques as support, preparation and enhancement of bio-medical availability of subsequent intervention steps.
- Environmental exposure controls such as use of headsets on cell phones, mitigation tools for eliminating sources of electro-magnetic fields, altering electrical and power circuits in sleeping areas, elimination of smells and fragrances in living space, and mitigation of environmental insults including mold and microbes.
- Applied Behavioral Analysis (ABA), Cognitive Behavioral Therapy (CBT), and other symptom management interventions.
- Nutraceuticals, probiotics and other medicines addressing underlying pathology that can be ingested as either sprays or capsules.¹⁹

There are no identified special risks associated with these interventions beyond those derived from individual preference and choice. The decision to use any, all or none of the interventions offered is left completely to the participant. In cases where the participant has questions or concerns about an intervention option, 'guides' will facilitate seeking out answers to those questions for the participant.

¹⁸ Self selection into protocol groups will be reflective of financial means, willingness to follow the protocols, and other 'real world' variables that contribute to the quantification of outcome effectiveness.

¹⁹ Use of prescription medications will derive from consultation and agreement of each participant's personal physician.

ANTICIPATED BENEFITS TO PARTICIPANTS

The intervention protocols and integrative pathways being studied in this research have been used in varying degree over the past several years around the world in assisting those with the various types of environmental illness encompassed within this work. The arrays of interventions are uniquely convergent in addressing the common underlying pathology in these conditions of cell membrane oxidative stress.

Many people who have followed various versions of the protocols have seen reversals of their symptoms and improvements in their conditions. Some of these reversals have been dramatic. Others who have used the protocols have not accrued as strong benefits. The purpose of the study in this regard is to allow the 'data to speak' in terms of the effectiveness and the efficiency of the protocols and pathways as well as the guided self-help delivery system.

ANTICIPATED BENEFITS TO SOCIETY

Mental health illness presents difficult challenges for medical professionals. Many times, traditional interventions worsen some of the oxidative stress reactions and thus exacerbate symptoms. In addition, many of the alternative or integrative intervention tools that have shown promise in managing mental health illness are not covered by insurance and therefore out of the range of options for many people who do not have means to pay for additional care. This creates a health care delivery inequity, the burden of which falls on those underserved and underprivileged. Participation in this study will help balance this inequity.

Health care is moving strongly toward 'evidence-based' interventions and 'best practices' designations based on comparative effectiveness research as key parts of determining insurance coverage eligibility. Integrative medicine approaches to these types of diseases are very difficult to study and for that lack of data, are sometimes denigrated as non-science or quackery. The work encompassed in this study is designed to produce 'evidence' consistent with the criteria used by private and public health care payers in deciding what is covered and what is not. Providing such data will level the playing field for integrative choices, hopefully leading to insurance coverage for these interventions and other interventions aimed at mental health wellness.

FINANCIAL ASPECTS AND OBLIGATIONS

This study is not funded at the present time by any outside sponsor. However, this work is critically important in terms of addressing the emerging health care burden of mental health illness. In addition, the research is time sensitive in terms of the opportunities presented by current efforts for health care reform. These considerations have led SPPI to commence this study in lieu of waiting for other government or private sector funding. Therefore, the costs of the study are jointly borne by the non-profit Science and Public Policy Institute and the participants. SPPI is covering the scientific aspects of the work with its contribution of resources. Collaboratively, each participant will contribute a participation fee that covers the professional services you will receive in the study process over the 18-month study period.

It is possible that your insurance will pay for some or all of the interventions and tests you will receive if you participate in this research. Conversely, your insurance may not cover any of the

costs at all. That is because many insurance companies, HMOs, and health benefits plans do not cover experimental programs or do not recognize the conditions being considered in this research as compensable. In any case, the research team will do its best to help achieve insurance coverage for your participation.

The charges you will have to pay, either through insurance coverage or personally, will be as follows:

- \$750 participation fee that covers your initial and ongoing evaluations and other costs associated with your enrollment in the study and following your progress throughout²⁰
- Standard costs for treatments such as acupuncture, massage, chiropractic and other integrative interventions that might be part of your pathway
- Purchase of intervention tools such as fragrance-free soaps, lotions, deodorants, laundry detergents, cell phone headsets, electrical kill-switches or filters and remediation of mold and mildew.
- In cases where necessary, laboratory tests
- Nutraceuticals, probiotics and other medicines that range in cost from \$40 to \$60 per month at the early stages of the study and up to \$150 per month at the late stages of the study
- In cases where participants wish to leave the study after they have received their evaluations and intervention protocols, there are will be no refunds of the participation fee, although further costs will be avoided.

Those who wish to participate in the study but do not currently have the financial means to cover their contribution to their participation are offered two options:

- Option 1: make progress payments toward the participation fee, and once that amount has been reached, you will be invited into the active study pool so long as the study is in the phase of admitting new participants.
- Option 2: be placed on a study eligibility waiting list in order of the date of your agreement to participate.²¹ The SPPI will actively seek out benefactors to cover the costs of individuals so challenged, and those on the waiting list will be notified when funding for their participation is secured and they will be entered into the study at that time so long as the study is in the phase of admitting new participants.²²

It is estimated that the total cost, combined insurance reimbursed and out-of-pocket, for any person participating through the full 18-month length of the study will on average be approximately \$2,500. This amount may not be in addition to current expenditures, but may take the place of some current expenditures on medicines and remedies no longer needed in the study protocol.

²⁰ Protocol pathways addressing mental wellness in children or other immediate family members include interventions aimed concurrently at those participants. As such, the participation fee for the second and other subsequent participants is reduced to \$200 for additional participants after the first.

²¹ Basic financial information will be asked for to help determine financial means and needs.

²² It is important for the scientific integrity of the study that all participants are situated as similarly as possible in terms of financial coverage as they move through the study. Those who are funded by a specific benefactor will have a defined amount of funds dedicated to their participation so they too will have to choose which interventions are applied based on there affordability.

Payments to the study can be made via PayPal, credit card or check. Checks will be cleared through online monitoring, and information required for that process is required.

PRIVACY AND CONFIDENTIALITY

The only people who will know that you are a research subject are members of the research team and if appropriate your clinician. No information about you, or provided by you during the research, will be disclosed to others without your written permission. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audio tape recordings of you will be used for educational purposes, your identity will be protected or disguised.

The study will enlist participants beginning June 15, 2010 with open enrollment through at least December 31, 2012. The first analysis will be done at that time and the final report will be completed within four months following. A summary of the report will be made available to participants upon request.

Participation in this study is entirely voluntary.

It is anticipated that benefits derived from the services received through the course of the study will be variable from participant to participant. Benefits to society of this research include the provision of data that will enhance the possibility of insurance coverage for the integrative interventions applied to the mental health illnesses within the study as well as lay groundwork for coverage of other interventions aimed at preventing, treating and otherwise managing mental health illness.

STUDY PERSONNEL CONTACT INFORMATION

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SIGNATURES – Mental Wellness Study

I have read (or someone has read to me) and understand the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form. I understand that the study team is not responsible for the decisions that I make through the course of the study and I agree to hold the Science and Public Policy Institute and the research team harmless for any discomfort I encounter due to my participation.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH AS IT IS DESCRIBED.

Print Name of Subject

Print Name of Legal Representative (if applicable)

Signature of Subject or Legal Representative _____
Date

Where did you hear about the study? _____

INVESTIGATOR OR INVESTIGATOR REPRESENTATIVE

I have explained the research to the subject or his/her legal representative and answered all of his/her questions.

Print Name of Investigator or Representative

Signature of Investigator _____
Date

APPENDIX

Environmentally Induced Mental Illness: Relevant Science

Traditionally, categorization of environmental illness has been limited to Multiple Chemical Sensitivities (MCS), Electro-Hypersensitivity (EHS) and other conditions with diverse and non-specific symptoms thought to be 'idiopathic'. However, new research makes it clear that influences of the environment on illness go far beyond this limited number of conditions. In its simplest definition, environmental illness is any condition for which the cause has not been shown to be genetic, and environmental science has now evolved to a content complexity that supports that simple definition. Within this definition, are mental illness and mental wellness.

All environmental exposures – including external insults from air, water and electro-magnetic fields as well as internal insults from ingested foods and pharmaceuticals – provoke cell membrane level adaptive responses. Maladaptation leads to disease; constructive adaptation tends toward resistance and immunity. Differences in adaptive capacity define why everyone who smokes does not develop lung cancer and why everyone who diets does not lose weight. The key is that the complex interplay of genetics and environment, including epigenetic mechanisms, synergies and effect modifications, defines adaptive capacity and therefore defines disease, illness, wellness and self-realization.

Following from this new knowledge, it is clear that environmental illness, including mental illness, in today's world is more pervasive than generally acknowledged. Autism, conditions such as ADHD and ADD, Post-Traumatic Stress Disorder, anxiety disorders, depression and sleep problems all have significant environmental components. Most cancers, reproductive problems and infertility are considered to have environmental etiology. Heart disease, diabetes and circulatory problems are related to internal environmental insults derivative of dietary practices. All tolled, more than half of all illnesses being treated everyday in North America, Europe and Asia can be classified as environmental. Adding to the complexity is the interplay among those suffering from conditions such as cancer and heart disease with the acceleration of depression and related mental disorders – people with terminal illness are at high risk of depression, for example.

Treatment and management of these conditions is difficult and success rates, irrespective of the public relations efforts of treatment providers proclaiming dramatic cures, are low. One reason is that consideration of the fundamental Bio-Energetic Loop (BEL) that underscores the organism/environment interaction is missing in most treatment and management protocols. The complexity of these conditions makes it important from a favorable outcome perspective that integrative interventions are covered in standard treatment coverage.

The BioEnergetic Loop (BEL): Relevant Science

The BioEnergetic Loop is the framework for the mind-body connection, and is the basis for how mental illness and physical disorders are related. It is also the basis for comprehensive approaches to mental illness treatment and mental wellness enhancement.

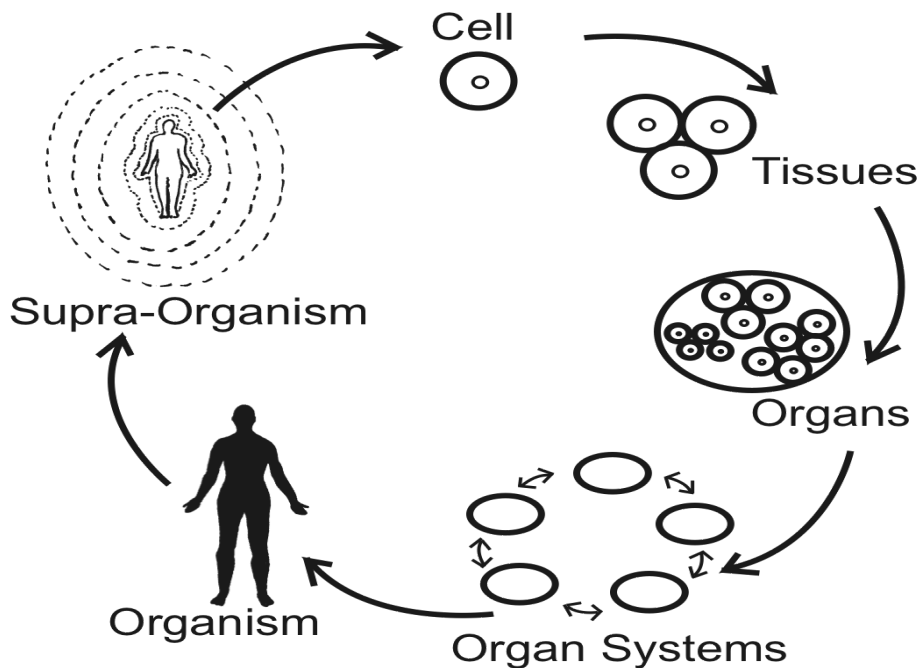
Energy potential differences across cell membranes have long been known to play important roles in cell structure and function. As biological knowledge has evolved, it has also become clear that virtually all reactions in physiology are the result of energy transfer, including making and

breaking of ionic or covalent bonds, free radical reactions, and osmosis. Thanks to the work of luminaries such as Drs. Fritz Popp and Bruce Lipton we now understand that light energy in the form of biophotons is also integral to organism physiology and that the cell membrane is the focal point for cellular environmental monitoring. In addition, research shows that energy potentials across cell membranes are variable over time, depending on whether a cell is in a parasympathetic (relaxed) functional state or in a sympathetic (stressed) reactive state. When the cell is effectively 'relaxed' the energy potential and resultant kinetic energy is greater than when the cell is 'stressed'.

These collective findings have been critical to understanding the BEL. Individual cells function in coordination with neighboring cells. The means of effecting this coordination is intercellular communication. We now know that intercellular communication is achieved through at least two distinct types of reactions. The first is an energetic communication that is bio-photon based. The second is biochemically mediated through gap junctions and connexins, depending on the type of cell. Most important is that the combination of light energy and chemical energy transfer makes intercellular communication effectively instantaneous.

The Bio-Energetic Loop (see figure below) is the means through which any external or internal environmental stimulus is able to instantaneously cause a cell membrane level reaction under certain circumstances defined by the characteristics of the person at a specific point in time. In short, the BEL is the connection between cells and the environment. Cells communicating with each other to effectuate joint function form tissues. Cells and tissues communicating with each other to effectuate joint function form organs. Organs communicating and functioning together form organ systems. Organ systems working together define the organism or in this case, the person.

Bio-energetic Loop



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At each level of coordination is a transfer of energy that effectuates a transition of cell membrane energy potential to kinetic energy. The sum-total of the kinetic energy scaling from cells to tissues to organs to organ systems to the organism forms a bio-energetic field that radiates a distance away from the corpus or body of the organism. This supra-organism or bio-field can be measured and in most cases it radiates from six inches to about three feet, depending on variables including the person's health status, activity and level of sympathetic stress. Internally, the bio-field reaches across the digestive and excretory tracts.²³

Evolutionarily, the BEL is a multi-level protective system for the organism, with the ultimate protection aimed at keeping individual cells from being damaged. The first line of defense or the first level point of adaptive response is the bio-field – both external and internal. For example, a bio-field response explains why people can 'feel the energy change' in a room when an argument ensues (external bio-field reaction) and why people feel queasy in their stomach when they see something that makes them nervous (internal bio-field reaction). The purpose of this reaction is to provoke in the organism (person) a 'protective response', usually an avoidance response.

If there is no avoidance response provoked by the bio-field level warning, then the organ systems take over – for example, initiating an adrenalin release provoking cardiac and circulatory system changes to facilitate 'fight or flight'. The protective layers scale down to the individual cell, where lipid peroxidase reactions effectively close cell membrane ion channels as the last line of defense. The protective cascade is a continuum where each insult impacts the entire BEL to varying degrees.

Using the BEL in Treatment, Prevention and Wellness

The key to applying knowledge of the BEL in preventing, treating and managing mental health illness is in understanding that the BEL defines what level of the organism can be accessed with an intervention at a given time. Whether an intervention is physical, chemical or biological, the organism's initial response is protection against a potential environmental insult. Thus, with any intervention, the BEL protective cascade is initiated. In addition, residual environmental insults present at the time an intervention is introduced play a role in determining the level of access within the organism.

For example, successful treatment and management of condition with mental illness components such as Autism, MCS and EHS require elimination of both chemicals (including fragrances) and electromagnetic fields from the person's environment as well as other sympathetic stressors while the interventions are introduced. Cell membranes are the site of the operative pathology, and to reverse these conditions, cell membranes need to be accessed. If the person is in an environment where the bio-field avoidance response is not possible, organ systems and organ protections prevent efficient cell membrane access. Ingestible supplements to increase cellular energy, for example, would not be taken up by cells because cell membrane sympathetic stress reactions would reduce cell membrane permeability.

²³ From an embryonic development perspective, the digestive and excretory tracts are 'external' to the organism, the result of internal folding of ectoderm and endoderm. Thus, it follows that the biofield is the result of cumulative energy radiating outward

As a practical matter, addressing interventions over time from the outer layers of the BEL to the inner layers has shown the most promise in efficiently managing mental health illness. Outer layer interventions include many integrative approaches including acupuncture, network chiropractic, standard chiropractic, massage therapy, homeopathy, and Reiki. After a period of time, inner layer interventions such as nutraceuticals, probiotics and other medicines can efficiently be added and are bio-medically available to do their jobs. The goal is to achieve bioenergetic balance throughout the course of intervention and this is best achieved by using the BEL as a roadmap to intervention choices.

Guided Self-Help versus Clinical Supervision

People who suffer from mental health illnesses, knowingly or unknowingly, face difficult challenges in the traditional western health care delivery system. These challenges include difficulty in establishing diagnoses as well as the absence of understanding among many clinicians about environmental causes and influences on these types of disease. As such, many with these conditions seek out information on the Internet and other easy-to-access sources to become informed so that they can treat themselves or, in the case of parents, treat their children. Unfortunately, much of the information easily accessed is unfiltered, not peer reviewed, and many times fraudulent or otherwise misleading as it is offered to sell products and services.

Nonetheless, with no where else to turn, far too many of these patients expend personal resources to exhaustion out of desperation to help themselves while seeing very little health and quality of life improvements for their efforts. Many others are not aware that their symptoms and health challenges are environmentally induced and many times receive treatments and medications that are contraindicated for mental health related illness. In these cases, the 'wrong medicine' serves to exacerbate discomfort, symptoms and the underlying pathology.

An important part of this present research relates to empowering those who are able to assimilate and then use intervention information on your own to help manage mental health illness. Studies and clinical experience over the past five years show that in all age demographics, especially the under 50 age group, a significant proportion of people prefer to be empowered to help themselves with regard to their health and wellness rather than depend exclusively on advice from clinicians. Successful interventions leading to illness recovery and risk management occur under both delivery mechanisms; however, it is believed that higher levels of efficacy are achieved when the patient or person sustaining the interventions are in a program consistent with their comfort levels and belief systems. There are many variations of health intervention delivery, including: visiting a clinic or clinician and receiving advice and guidance under their direction; visiting a self-help website and following iterative advice offered there; and ordered conveyance of fundamental, but scientifically rigorous, information for application to guided self-help.

This research is addressing the third option delivery system that is the most 'hands-off', self-empowering in terms of direction, and resource conservative in terms of health care costs.