

# Ethics & Nonpharmacological Interventions in Dementia

*John Zeisel, Peter Whitehouse, Barry Reisberg, Robert Woods, Ad Verheul*

*Manifesto—a written statement declaring publicly the intentions, motives, or views of its issuers*

## Introduction and Overview of the ethics paper

**Write a summary introduction here.**


### Terminology

Labeling caregiver training, art museum tours, and environmental design interventions in dementia care as not being drug treatments avoids addressing the nature of such actions—what they “are”. Employing the label “nonpharmacological”—a term that defines its subject in terms of what it is not—belittles the positive nature of the interventions themselves.

“Nonpharmacological” interventions in dementia care represent much more than just what remains when pharmaceutical interventions are taken out of the equation. The question of terminology raises ethical questions—such as how labels might limit availability of resources, limit knowledge of potentially significant research data and evidence, and limit access to treatments that might provide those with dementia and their partners a higher quality of life and a life worth living.

This does not mean that we can just disregard the existing terminology. The term is being increasingly used in research literature on dementia care (**list five recent references.**) Cohen-Mansfield, for example, in a recent article in the *Gerontologist*, employs the acronym “NPHI” (Nonpharmacological Interventions) for her study subject (Cohen-Mansfield et al, 2012). And the term “nonpharmacological” is increasingly being employed in scholarly and professional publications to describe a range of interventions in the treatment of ADHD, asthma, high cholesterol, pain management, labor, and other conditions (cite references). In addition to the ethical issues raised by the term, it remains conceptually inelegant—a commonly accepted shortcut that really does not adequately describe the phenomena it refers to. The short cut, to continue the metaphor, may end up taking more time than the direct route.

The following discussion proposes that the term “*ecopsychosocial*” replace the term “nonpharmacological” in both research literature and common parlance.

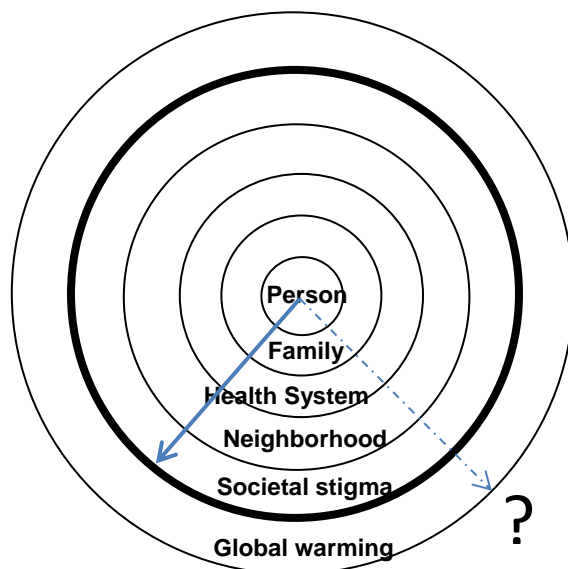
One term often proposed and employed for the realm of intervention with which we are concerned is “psychosocial”. “Psychosocial” is appropriate to describe those “nonpharmacological” interventions that intervene directly in a person’s psychological state or social situation or improve a person’s psychological state and social situation. Not all “nonpharmacological” mechanisms do this. Effects of certain nonpharmacological interventions are biological. The term “psychosocial” clearly does not apply to them. For example,  intergenerational schools and museum visit programs are interventions that encompass a great deal more than the purely psychological or social. The term “psychosocial” is ultimately inadequate because environmental change is missing. It does not adequately encompass interventions that make changes to the person’s context including environmental design, introducing a new object such as a “memory book” into the setting, or adding music or art.

Another term—“ecological”—refers to “the relationships between organisms and their environments” and to the study of “the relationships between human groups and their physical and social environments” (ref “The Free Dictionary” website). Frequently employed in biology, sociology, and psychology to indicate contextual factors, it might well be the solution to our terminological dilemma. Since many interventions considered “nonpharmacological” are concerned with changing the environment of people with dementia—physical design, staff training, family counseling, as examples—it would appear that a reference to “context” is required in any term to replace “nonpharmacological”.

For these reasons, among others, the term “ecopsychosocial” seems an excellent replacement for the present term “nonpharmacological”. It is more comprehensive, indicating the broad range of interventions in this class of objects. It positively delimits a category of object, independent of what it is not. It can serve to draw together for research purposes a comparative group of interventions—leading to more shared methods and comparative studies.

### **Range of “eco-psycho-social” (EPS) Impacts & Outcomes**

Including environment as a factor through use of the term *ecopsychosocial*, raises the question: What scale of environment, what environmental range, ought to be considered when defining the environmental concerns included in ecopsychosocial interventions? What is the ethical environmental range of the “dementia problem”?



***Environmental Range of Eco-Psycho-Social Interventions in Dementia***

Clearly the person at the center of the diagram, his or her family and the health system in which they live are part of the “dementia problem” environment. But what about the neighborhood and the larger society; are they part of the definition of the problem and of potential solutions? Neighborhoods are part of this problem/solution set because if neighborhoods were better equipped to respond to the needs of this population, those living with dementia would be more likely to use the physical and commercial environment adjacent to their homes. Society is also clearly part of the problem/solution set because social policies affect those with this condition and the stigma associated with the disability is a barrier to their social integration.

An argument can be made that urbanization, air pollution and the way our food is handled and sold are all part of the “dementia problem.” Taking the problem to this level, however, runs the risk of diluting advocacy to the point of absurdity. For example,

all the wood fires in rural India taken together contribute significantly to global warming, which in turn is linked to urban life, which is linked to high cholesterol and diabetes—both of which are linked to dementia. To attack wood fires in rural India as part of an effort to combat dementia seems more like creating a problem than finding a solution.

A strong argument can be made that ecopsychosocial is an ethically inclusive term useful to describe the broad range of environmental, behavioral and training interventions that help people with dementia, and that the largest practical environmental scale to consider is “society.”

### **The terms dementia & Alzheimer’s**

What a condition is called and how it is labeled also has ethical consequences. Different countries employ different terms for the condition of dementia. Some use “dementia”; others “Alzheimer’s disease”; others only “Alzheimer’s”. The US used one term decades ago—“Alzheimer’s disease and related dementias”—and uses another today—“Alzheimer’s.” If people—professionals, family members, care givers and policy makers—do not embrace a single consensual multi-national vocabulary, it is unlikely that they are going to be able to communicate with each other globally for the benefit of all those living with cognitive decline.

### **What does dementia mean?**

- Dementia—absence of mind (“more mad” derived from Latin”)
- Amentia—without mind
- Major neuro-cognitive disorder
- Cognitive decline
- ”Ageing of the brain”


Each has implications for the way dementia is seen and dealt with.

## What is the condition called?

- A disease?
- An illness?
- A disability?
- A condition?

Each has implications for the way dementia is seen and dealt with.


## The importance of the terminology issue

In the social sciences and particularly in the social science specialty “symbolic interactionism” based on the writings of Howard Becker (Citation) the study of “labeling” is a formal discipline. Labeling theory examines how the terms we invent and employ for various conditions influence our perception of those phenomena, how we respond to it, and how we create social structures to deal with the phenomenon labeled in one or another way. A recent and pernicious labeling event  that everyone is familiar with is the term “terrorism” that has become popular since 9/11. We are all familiar with the institutions that have grown to combat terrorism—not the least of which is the Transportation Security Administration (TSA) we meet at every airport and the Department of Homeland Security in the US. In the medical profession, such labeling and re-labeling goes on continuously. The labeling of “homosexuality,” once considered a mental illness, is just one example. In dementia, such a re-labeling is taking place at present with the latest draft of the Diagnostic and Statistical Manual (V)--(DSM-V) suggesting that the term dementia be replaced with the category *Major Neurocognitive Disorders*.

## “Labeling” history of Alzheimer’s disease *(needs expansion)*

1906—Alzheimer’s discovery of plaques and tangles

1910—Krepelin’s textbook

1979—UK Alzheimer’s Society—decision to call it “dementia” 

Date—US Alzheimer’s Association—decision to call it “Alzheimer’s”

1981-1983—Bob Katzman

Date?—*Bernard Isaacs* “brain failure”

## **Cognitive Decline: The cardinal issue**

Cognitive decline (CD), the cardinal issue of both dementia and Alzheimer's, is a label making explicit that the condition of dementia is a process in which mental capacity decreases progressively. The term itself references conditions that become worse slowly over time, unlike an electric current that can be turned off or on with a switch. Dementia, Alzheimer's and now Mild Cognitive Impairment (MCI) refer to mental processes that gradually change—processes—like an electric light dimmer switch. And the light starts to dim long before any official “diagnosis.”

## **Mechanisms for people to address Cognitive Decline health issues**

In most societies formal mechanisms exist—called Advance Directives—that people can use to plan and decide their own future, including what to do in case of ill health and cognitive decline. All such mechanisms present us with the same ethical dilemma—what if the person when in sound mind feels one way, but feels another way when experiencing cognitive decline? For example a person might say—“I would rather die than have Alzheimer's disease,” but when in Cognitive Decline say that she is having a good time and likes her quality of life. And what if the person who must make a decision, for example that the other not be resuscitated, has gained a new appreciation for the relationship to the other, to a mother for example, in cognitive decline and does not want to fulfil her obligation. In both situations a thought or feeling before dementia might well have changed when a decision is necessary. What should one do?

- *Advanced Directives* are documents in which a person can explain his or her wishes regarding how to be treated if and when a certain health condition arises. This might include whether the person wants to be resuscitated if they experience heart failure after a certain age. It can also include what to do if the person experiences a major cognitive decline.

Advance Directives, in most societies are not legally binding and present significant ethical problems when cognitive decline is concerned. Persons with no cognitive decline often cannot imagine life without the ability to plan and recall


everything easily. Later, many of the same people living with dementia can have a relatively enjoyable life. This dilemma needs to be part of any discussion of dementia ethics.

- *Decision-making transfer*, in case the person has reduced ability to make complex decisions for him or herself, is commonly accomplished in three ways. Each mechanism assumes that the person to whom responsibility is transferred knows what the person him or herself would want to happen. *Power of Attorney* transfers to another the legal right to make all decisions for the other person—financial, health, residential, and so on. A *Health Care Power of Attorney* is equally legally binding, but allows only for health related decisions to transfer. A *Health Care Proxy* is even more limited, transferring only the right to make health related decisions for the other and then not legally binding.

Essential in these situations in order to grapple with the ethical dimension of decision making, is that grand generalizations and vague principles be avoided in transferring decision making power. “If I get Alzheimer’s” is such a generalization. “If I can no longer make decisions for myself” is another. “Never put me in a home” is still another.

Including personal stories is one way to communicate wishes more completely. Life-scenarios of loved ones we know or of specific situations that a person can imagine in such documents helps the person later making a decision to weigh how a present situation actually compares to what the other might have foreseen—what the other had in mind. It also gives greater guidance to the person making decisions for another as to values and mental pictures the person has that he or she wants to convey. Scenarios like this also give the other latitude to more personally interpret situations they face related to the other by comparing scenarios.

Proposed then is to replace “Nonpharmacological interventions to dementia” with “*ecopsychosocial (EPS) interventions for cognitive decline (CD).*” Because “cognitive

decline” uses the process term “decline”, it encourages inclusion of behavioural and mental health—rather than focusing only on a person’s cognitive abilities or losses 

### **Social justice issue:**

Employing the term “cognitive decline” also impacts whether “the person with CD” is able to receive and receives existing services from the existing health system of which they are a part. People with dementia face chronic conditions like confusion and acute health care needs such as a heart failure of some sort or help with injuries suffered from a fall. These acute health care situations often require emergency attention delivered in a hospital Emergency Room. Appropriate health care in non-dementia-specific settings like an Emergency Room, requires that the health care staff in such settings understand and are trained to recognize and deal with those among their clients with cognitive decline and thus with different needs than their “normal” clients. For example, Emergency Rooms often have a rule that only family members may accompany persons into the clinical setting. This assumes that the patient does not actually need another person with them, but rather that the family member in the treatment room is an extra benefit. But a person with dementia / cognitive decline might require a companion for successful treatment, whether a family member, paid companion or friend. Such rules focusing on “family members” are not dementia friendly. Staff members need to be trained to know that any accompanying person ought to be allowed in with a person who has a dementia to help the person with CD to remain oriented. Staff persons in mental health settings need training to realize that the “hallucinations” a person with dementia might have are different from those of someone with another mental illness?


### **Cognitive Decline**

The term “cognitive decline” might not only be the most accurate term for dementia and Alzheimer’s, it may be the most ethical. First, it is a term that even an untrained layman can understand with little explanation. There is less mystery. “What is the difference between dementia and Alzheimer’s”, many people ask. Second, the term focuses attention on the major symptom of all dementias—level of cognitive ability with its many behavioural characteristics. This logically links extreme conditions of cognitive decline




such as early onset dementia “of the Alzheimer’s type” to other states of cognitive decline, making it easier to compare and contrast conditions and treatments. For ecopsychosocial interventions this is significant given that many ecopsychosocial interventions and approaches are applicable as treatments for all conditions of cognitive decline—not just Alzheimer’s but also for or Parkinson’s dementia, HIV/Aids related dementias, and others


### **Health Literacy**


All health care settings will increasingly be required to provide medical care—not dementia care but general health care—to persons with dementia. Dementia care does not take place anymore only in a dementia care setting. Facing this onslaught  bureaucracies such as hospitals as well as individual hospital departments often face an additional challenge, namely to defend their turf against shifting policies and demands. Emergency rooms, hospital wards, diagnostic laboratories all have their individual mandates requiring them to focus on particular aspects of ill patients. But, dementia is so pervasive that existing health systems and their components departments must be prepared to deal with clients who also have dementia. Being prepared to meet the health needs associated with dementia often means seeing and dealing with persons with dementia as whole persons—not in terms of their one or another specific health problem. People with dementia often have difficulty being treated as “the broken arm” or the “heart case.” They see themselves as whole and when they face difficulties understanding where they are and that they are not being treated as a whole person—something others without dementia may better tolerate—it is much more disconcerting to them.

Medical staffs also must address the attitudinal component of their work with people with dementia. Health care providers need to better understand that persons with dementia are persons first and someone with dementia second. Given the stereotyped and stigmatized views so many people generally hold of persons with dementia—often focused on losses and disabilities—such attitudes are likely to prevail among health care workers if there is no concerted training effort to change this.

Much has to be done to make sure health care workers generally  that people with dementia can do, not only what they can't.

### **Human Rights—perhaps the core ethical question in dementia care**

Clearly the characteristics of successful ecopsychosocial interventions—that they improve a person's quality of life, that the person's life is more “normal”  that the person is treated with dignity and respect—describe well what it means to be human. These serve well as the primary criteria for judging the success of ecopsychosocial interventions in the lives of people with cognitive decline. A worthwhile and normal life, relationships and dignity, and the opportunities to flourish and be celebrated, are the ethical goals for all people with cognitive decline as well as all of humanity. Being able to provide such a life for those with cognitive decline requires that each person's level of capability be recognized, given the opportunity to succeed and be celebrated.

When people change with cognitive decline there are alternative ways to define the changes other than just labelling them as symptoms of an illness or disease. The best for the person, the ethical choice is to see the changed person. As a new person, not an un-person. She can be seen as an evolving person living a life that is celebrated.  Regardless of the level of a person's cognitive decline, everyone with dementia has legitimate expectations to be treated as a whole person.

Ethically this definition greatly supports the human rights of those with cognitive decline.

### **Celebration of Life—birthday party ethics**

**INSERT NEW SECTION HERE**

## **Cure & treatment—both pharmaceutical & Ecopsychosocial**

Everyone wishes there were no dementia, regardless of their professional or personal role in the “dementia industry.” Even those who make a living from Alzheimer care—pharmaceutical companies, management companies, researchers, care givers—do not hope this condition continues, just in order to make a living.

The growing set of voices recognizing the lack of progress towards a “cure” for Alzheimer’s and other dementias is not coming from those with a self-interest in dementia care. These voices do not reflect self-interest, but rather are the voices of most people reflecting the blatant reality that none of the present medications aimed at improved cognitive functioning substantially improves the quality of life of those living with dementia.

Despite loud self-congratulatory announcements that more and more countries are developing National Dementia Plans that include deadlines for “defeating Alzheimer’s”, the actual likelihood of reaching these goals in the foreseeable future is small.

Cure, basic science, and research efforts to delay onset clearly are aimed at improving the chances that future generations might live without the present high chance of having a dementia as we age. So much finding and so many policy efforts are aimed at speeding up the development of cure/delay research that these efforts dominate the realm of discourse over the airwaves and in news articles, policy initiatives, and popular awareness. The cure / delay research agenda dominates the dementia research discourse.

On the other hand, ecopsychosocial interventions and research, while concerned with future generations as well, aim directly to improve the lives of those living with dementia today and in the foreseeable future. Ecopsychosocial interventions change the context (eco) of those with dementia, modify their social lives (socio), and influence their partners’ attitudes and perceptions.

Despite increased national and international funding for biochemical bench research, pharmaceutical trials, and cure / delay research, these efforts move painfully slowly. The fact that these areas of research dominate the discourse that surrounds dementia policy creates a resource gap for ecopsychosocial research.


*Resource allocation:* It seems unbalanced that resource allocation for dementia research and development do not fairly weigh the value of positive results for both groups who might potentially benefit—future generations that cure/delay researchers hope will benefit from their discoveries, and those living with dementia today and in the near future who will definitely benefit most from advances in ecopsychosocial research.

*Hope, hype and false hope:* Cure/delay and basic science dementia researchers, in order to be self-motivated and to motivate funders, must hold out hope of positive scientific developments. Without hope of a better future, there would be no such investment. Except for the most cynical of all such researchers, hope among bench and other scientists is natural and healthy.

Sometimes hope becomes false hope and hype. When hope is personal, it clearly presents fewer ethical problems. I can hope for good weather tomorrow, to avoid ill health in the next decade, and for my children to be safe, all as a personal matter. Such hope has little impact on others. But when our “hope” becomes public and, because of our social roles and status, people listen to our “hope” as a rational and weighed prediction of the future, we run the risk of creating “false hope.” This is also not necessarily a social problem, as long as others recognize that our “hope” is exactly that—a wish. But it represents a major social problem when others, change their policies and behaviors based on our hope which they see as expert opinion.

In dementia circles, the public relies on scientists’ pronouncements about what a likely future might be. When the statements they hear on the media or read in newspapers predict “a cure is likely within five years” or a “we will conquer Alzheimer’s by 2025” they

believe it. It is irrelevant to the general public whether a person makes predictions because she believes them, because she hopes a desirable future will be the case, or whether it is a point of view bolstered by scientific fact or by a desire to maintain a high level of research funding. The responsibility is heavy this places on the shoulders of those whose position in the scientific community gives them status as reliable prognosticators.

**Quality of Life—a primary goal of ecopsychosocial interventions:** Living with dementia is not easy. Not only does the condition increasingly make it difficult to do things that you used to do easily and automatically, but the context changes as well—what is expected of you, what supports are available, how people relate to you. In order to develop interventions that improve people’s quality of life there must be agreement on the definition of a *worthwhile* and *normal* life. 

*Cultural norms and quality of life:* Dementia is obviously a global problem, but it does not necessarily follow that care and other ecopsychosocial solutions are amenable to globalization. Care and ecopsychosocial interventions cannot be homogenised. Personal experience tells all us that different ethnic and cultural communities often have differing definitions of a *worthwhile* and even a *normal* life. Worth, value, and quality are often subjective criteria.

In Korea, for example, in a highly valued residence for persons with dementia, there is little furniture, some low tables in the room, and elders crawl on the floor. The floor was clean, but the behaviour seemed demeaning to an observer from another culture. This is explained culturally by the fact that among elderly Koreans of that generation moving about and sitting on the floor at a low table is culturally acceptable, not demeaning at all.

In India, elders with dementia slept under rather than on the bed they were provided. This is also culturally explained as --- **Peter Whitehouse please clarify or another.** Although less dramatic in its difference, the same is true for the ways people with dementia are treated in European countries, or South America or Africa.

In sum, while ethical issues are universal, their translation and application must respect cultural diversity in the context of cultural values & practices. To adequately address this global issue, the professional community requires a common language and set of concepts so that we can learn from each other. Only then will we be able to develop in earnest much needed global and universal approaches to cognitive decline that apply well in all cultures and to all people living with dementia.

### **A Legal Framework**

One way to classify human rights in broadest terms is to employ terms of the law which summarize universal human rights:

- *Autonomy—define?*
- *Beneficence—define?*
- *Justice—define in this context.*

Employing a simple structure like this is one way to clarify the human rights of people with dementia and make evident that they, like everyone else, deserve these rights.

### **Ethical Approach to basic research in dementia**

#### **Epistemological ethics**

“Epistemology (*cite Wikipedia*) , derived from the Greek [\*ἐπιστήμη\*](#) (*epistēmē*), meaning "knowledge, understanding", and [\*λόγος\*](#) (*logos*), meaning "study of", is the branch of philosophy concerned with the nature and scope (limitations) of knowledge. It addresses the questions:

- What is knowledge?
- How is knowledge acquired?
- To what extent is it possible for a given subject or entity to be known?

The term epistemology, sometimes referred to as the *theory of knowledge*, was first introduced by the Scottish philosopher [James Frederick Ferrier](#) (1808–1864).

If we want to cast the broadest research net to catch the greatest number of high quality interventions, it is important to have a broad definition of acceptable research methods and methodologies. These are needed to capture as much data as possible that might provide answers to help people with dementia either at present or in the future.

Employing a Random Control Trial methodology to study basic dementia research questions is clearly ethical. To limit the definition of “knowledge” is not ethical. The breadth of research required by dementia studies must also include “empiricism”—observation and data gathering unencumbered by theory and other conceptual bias as well as other methods from case studies to large scale experiments.

Advances in astronomy for centuries have been based on careful empirical observation. Ptolemy and Galileo did not carry out random controlled trials to identify the planets and figure out that the world was neither the center of the universe nor flat.

As long as there remains in the minds of scientists and policy makers an *epistemological hierarchy*—ranking some knowledge as more valid and reliable than other knowledge—potentially game-changing know-how is likely to be overlooked. Given the narrow definition of “gold standard” knowledge, this is highly probable. If someone only looks for a lost item using a limited number of tools, it is logically probable that it will take her longer to find what she is looking for than if she used a variety of tools.

### **Ethical issue including cost/value:**

One important ethical issue relates to the cost and value of various research approaches. Simple empirical observation research into uncharted intervention areas can often have great value. Large scale RCTs, much more costly, often in the millions of dollars each, may or may not yield value. A thorough ethical discussion of the epistemological dilemma would include an in depth analysis of national / societal expenditures in intervention studies employing different methodologies, including RCTs, to determine the cost to benefit ratio in solving the human needs of persons with cognitive decline /dementia. At the simplest level, the benefit to cost ratio of loving care

between partners and people with cognitive decline might well be astronomically higher than those of most research.

## **Clinical Trials**

*Clinical trials*—usually large scale random controlled studies, sometimes blinded and always with some sort of control to assess actual effects of the intervention—are a well-accepted popular way to test interventions that potentially may help people with cognitive decline. The goal of most interventions studied in this way is to slow down the rate of decline, improve persons' quality of life, and otherwise improve a person's life. As the methodological section of this manifesto makes clear, there are other meaningful ways to approach the question of intervention efficacy that must also be considered. Ethical questions arise when selecting one or another methodology as a gold standard.

*Hope:* Clinical trials are often presented as being carried out only on treatments—both pharmaceutical and ecopsychosocial—that have already demonstrated at least a limited measure of efficacy: delay or life improvement. Even tentative findings offer hope to people living with dementia / cognitive decline that interventions on the horizon might possibly help someone. They themselves are hopeful that if they happen to be in the intervention group and if the intervention actually has an effect, they will be helped personally. If the study finds an effect, subjects are likely to believe that there will be improvements for others in the future. Hope on its own can positively influence the way a person, a couple or a family deals with cognitive decline. Of course hope can have the opposite effect, as well.

*Other beneficial side-effects:* Participants in clinical trials may benefit in indirect ways. Participants receive *increased attention*, leading potentially to quality of life improvements because attention itself boosts their morale—in social science this is referred to as the “Hawthorne Effect.” They also receive laboratory testing of bodily fluids and imaging of their brains that can provide professionals conducting the study insight into their individual condition. Clinical trials bring people with cognitive decline



into closer proximity to experts and professionals who might counsel them and help them in other ways.

*Ecopsychosocial clinical trials:* The term “clinical trial” has been associated primarily with “drug trials” that focus on whether pharmaceutical treatments have effects on the progress of dementia and its symptoms. Clinical trials are expensive, and with greater availability of funding for pharmaceutical trials which, if successful, might earn millions if not billions of dollars, it is not surprising that most clinical trials are pharmaceutical.

Despite this common practice and understanding, the term and concept of clinical trials are not limited to pharmaceutical interventions. They are an equally valid way to establish the effects of ecopsychosocial interventions and treatments such as music programs ([reference](#)), environmental changes ([reference](#)), and education and training programs ([reference Mary Mittelman](#)). At present large scale government funded clinical trial investigations are being carried out to test the impacts of scripted improvisational engagement theatre programs for people with dementia ([reference the IMPROV Project](#)) and for reading materials at different levels of complexity and visual impact ([reference BOOKCLUB Project](#)).

*Ethical issues:* Few methodologies and research approaches that scientific communities accept today are inherently ethical or not. All badly applied research or research carried out in secret runs an ethical risk. For this reason *peer review* and *publication* considered essential to bringing a research project to completion, are especially significant for clinical trials where the participants / subjects have some level of cognitive decline. People living with dementia and their partners are particularly vulnerable and susceptible to even the slightest hint of help because they see their future as dim.

### **The Need for Transparency**

Clearly transparency is one primary answer. Research risks and potential gains must be openly presented. Among the probabilities and risks that need to be disclosed are:

- The probability of a subject receiving a placebo

- Whether the trial aims to determine that there are no adverse effects (Phase 1 trial) or
- To determine efficacy of an intervention (phase 3 trial) and
- The likelihood of side effects

Dissemination is also a potential area for ethical discussion. Are all results publically disseminated or just positive results? Are negative replications of a previously positive study reported? These ethical issues surrounding dissemination of and participation in research increasingly apply to all such studies—both pharmaceutical and ecopsychosocial, especially as the breadth of research methodologies being applied to interventions, cure and genetics research is increasingly widening.

### **Communication Issues Surrounding Dementia Research**

Assuming ethical conduct among the great majority of researchers—whether academic or commercial—a major area that requires ethical oversight is in public communication of research findings—an area presently with only journalistic oversight. Communication of results is often out of the hands of researchers themselves, and even when in their hands, is potentially tempered by personal interest.

The realm of research communication is an ethical minefield. Journalists understandably want their articles about research findings to be read; attractive and alarming headlines make this more likely. Those who manufacture and sell products that research supports—whether pharmaceutical or ecopsychosocial—have a natural interest in the research on their product being presented in the best light. Researchers who make a living from funded research have a natural interest in their research resulting in positive findings and receiving positive publicity.

### **Ethical Challenges Facing Ecopsychosocial Research**

In part because funding is scarce for ecopsychosocial research in dementia, what research is carried out tends to be small samples and seldom with controls. When the scientific community takes notice of this research it is often accompanied by a phrase

like “but of course these small sample findings do not prove cause and effect.” (Find an actual quote and reference.)


In part because such small sample research is not taken very seriously, claims for ecopsychosocial research—whether in the press or in researcher’s announcements—often go unmonitored.

### **Monitoring Dementia Research Outputs**

The claims for most dementia-related ecopsychosocial research as well as much pharmacological research seem to go relatively unmonitored. While scientific journals carry out rigorous peer review of articles before publication, and researchers are careful to release little information before publication—once a study’s “methods” and “findings” are published—the evidence itself, the claims made based on the evidence, and even the description of the research go relatively unmonitored—except in the court of public opinion. The relative lack of public research and scientific sophistication makes this judgment largely irrelevant—especially given how desperate much of the public is for “good news” when it comes to dementia and Alzheimer’s.

Clearly the first step in all this is for greater transparency and public education.

### **The need for an “FEA”—an FDA for EPS (Is this the right place for this here?)**

One way to achieve the transparency necessary to raise the scientific and practical level of evidence for health claims in ecopsychosocial interventions in dementia is to create an organization whose focus is only on such interventions—the evidence behind them, the claims made and the research approaches underlying their development and evaluation. An FDA for EPS (actually an FEA for EPS) would demonstrate to not only the scientific but also the general public that this area of research and intervention is taken as seriously as the pharmaceutical area is.  Rather than request governmental support for such an organization, funds might be generated by the EPS community itself, demonstrating clearly the intent of this community to be taken seriously.

## **Diagnosis, Early Diagnosis and EPS**

There is presently a strong push among many dementia specialists including most of the dementia-support organizations like Alzheimer's Associations and Societies and ADI: Alzheimer's Disease International that everyone with dementia be diagnosed and that the earlier the diagnosis the better—even before any behavioural symptoms are evident. Early diagnosis, as it is being promoted in the US, employs biomarker studies in which a spinal tap or other method is used to determine the amount of amyloid plaque in the brains of subjects, and on that basis to predict the likelihood of that person developing the behavioural characteristics of Alzheimer's. In most European countries, early diagnosis refers to an assessment when the first symptoms appear. In the official statements in the US surrounding the call for early diagnosis using biomarkers, such diagnostic methods are targeted solely at identifying likely subjects for research studies, not the general public.

The argument made for this approach is that most modern clinical pharmaceutical trials fail in having any major impact because—according to this argument—the trials were carried out too late in the progress of cognitive decline. Once behavioral symptoms are evident, the argument goes, the progress of brain degeneration has progressed so far that no medication can help.

Whether or not this will be borne out by the next decade of dementia research will be evident only in another decade.

For the time being, there are at least two questions regarding the ethics of this approach that must be raised:

1. What if members of the general public decide they want “early diagnosis” employing biomarkers or other means? And
2. What if, as is the case, is the ethical thing to do if someone gets an “early diagnosis” and then demands that something ought to be done to help her or him?

The scientific community promoting early biomarker diagnosis falls back on their assertion that the “rules” being written will limit such diagnosis to research subjects. Others, including many scientists and medical professionals, are less sanguine about this limitation. If people want and can afford a medical procedure they usually can get somewhere. Ethically, nothing can be done to prevent that.

Ethically, it is essential that the medical and support community have a clear answer to give to someone who, once diagnosed in this way, receives a “positive” result predicting with a level of probability that he or she will develop a major cognitive decline. Those who promote early diagnosis argue that even though no medication is available, early diagnosis gives the person and his or her partners “to plan.” But does *planning* only mean planning how to eventually give up one’s independence? Or does planning mean how to live as well as possible with cognitive decline? How to have a life worth living? Ethically, planning would include this positive approach. At this time, the only workable answer is that the person ought to turn to ecopsychosocial interventions focused on improving a person’s quality of life and at reducing common behavioral symptoms their applications. And if that is going to be done, it is essential that the evidence for such interventions be available.

Another reason that ecopsychosocial interventions must be adequately studied and understood, is that these approaches serve as essential building blocks to persons and their partners celebrating their lives and developing what many say is a close and rewarding mutual relationship.

In sum, ethical approaches would indicate that doctors and others, but doctors necessarily because they often deliver the news of probable Alzheimer’s disease, need to recognise the value of EPS in the context of elucidating an early diagnosis through current methods.

**Popularizing research Findings (Perhaps here or earlier)**

Ethical questions also arise when it comes to “popularizing” research findings—interpreting research reports for public consumption.

### **Decision regarding adopting EPS interventions**

Perhaps because there is no control over promoting what might be called “ecopsychosocial” nonpharmacological interventions, some like mind-stimulating video games or puzzle books are sold as if they were a preference item like a pair of luggage or a video game—despite the fact that they might be very effective treatments for dementia symptoms. While in a market economy anything legal can be sold as a commodity, there is an ethical difference between a health care item being represented more as a video game than a medical intervention.

### **Transparency**

Clearly one principle that must be embraced is that whatever is presented be as transparent as possible with one item being paramount: the transparency about if the intervention might possibly do harm. “Is there any harm to anyone involved?” must be the primary question posed to every public representation of this sort. The same must be applied to headlines—often written by someone other than the article’s author. Headlines that attract readers sell papers and magazines, so this is an accepted part of journalism. However when headlines promise a cure tomorrow when the research promises only small gains, the public can be confused. The more popular nonpharmacological interventions become, the greater the need for transparency.


Lay communities are becoming more knowledgeable about science and medicine in general. Perhaps one possibility would be to promote greater scientific knowledge among the journalists who write such articles and provide the headlines.

### **Funding: Priorities and Opportunity costs**

There is little question that funding for dementia research lags far behind funding for research into other physical and mental health conditions. For some time there have been calls for greater funding and the recently passed US National Alzheimer’s Plan

requests that millions of dollars more be committed to dementia research. The ethics questions surrounding this commitment of increased funding, focuses on what research is funded, what are the limits to that research in terms of subject and methodology, what is the relative research emphasis between preventive studies, delay studies, cure studies and nonpharmacological / ecopsychosocial studies? At this time greatest interest seems to be on pharmacological studies into chemical and other physical body fluid diagnostic procedures and potential cures and delays by vaccination or other means.

The question remains, what are the opportunity costs of this focus? Most people agree that, if successful, these studies will help future generations not the present generation of people living with dementia. In the meantime, the lack of emphasis and investment in ecopsychosocial research and the resulting lack of development of proven ecopsychosocial interventions are the lost opportunities. This factor needs to be part of the public and policy discussion on dementia research funding.

A basic structural question that must be raised is who—what professions and experts from what fields—ought to determine the realm of discourse on this and related issues of resource allocation, problem definition, priorities, and so on. As important in answering this question is the role of people with dementia in decision-making related to these issues, the points of view of partners and other family caregivers, and even  the role of women—a feminist perspective—towards these questions.

### **Training Differences**

Most if not all national dementia plans call for more training of caregivers on dementia care principles and practice. The present US National Plan is no exception, and much of the discussion surrounding dementia care and living with dementia include calls for more training. The material written on this subject seldom, if ever, discusses the fact that there are many different types of training available—and the points of view of different approaches can be extremely different. For example, the point of view that Alzheimer's is a continually declining illness with no possibility of quality of life leads to

training focused on the use of medications to alter the condition and the person's behaviour, practises related to physical care and safety, and ways to ease the person into the downward spiral as seamlessly and painlessly as possible. On the other hand, training based on a more positive and hopeful belief that a person living with dementia can fully experience a life of quality and meaning, would focus on mechanisms—mostly ecopsychosocial ones—that enhance life, add meaning, add fun and enjoyment, and improve the relationships between the person and friends and family.

The fundamental question related to training and the realm of dementia training discourse is who defines the types and range of training to be supported and offered to care partners and care givers? Especially who defines the theoretical and philosophical underpinnings of such training? This includes as a major discussion point the relative role of ecopsychosocial training and the requirements in all trainings to make transparent what is known and what is not known about all elements of training.

### **Is the “Long Goodbye” an appropriate metaphor for dementia?**

Many authors, journalists and people related to dementia have called dementia—the condition following any diagnosis, no matter how early—*The Long Goodbye*—after (or leading to) the book of that same title (reference.) Of course, dementia being a condition of cognitive decline needs to have a way of measuring or at least indicating how fast and how steep (or how slowly and how even level) that decline is. Many present categories are based on behavioural factors—what can the person do or not do for herself? Others aspects included are the degree of mental disturbances such as hallucinations? What is seldom measured is what the person **can do**, although such a scale will surely be developed soon.

Whatever the scale employed to measure the state of a person's dementia, if the future holds to form, how others treat him or her will depend more on that person's point of view than the state of the dementia. The long goodbye, as a metaphor for dementia, leads to seeing mainly deficits and increasing deficits in the person. Essentially this



metaphor means saying goodbye to the person's abilities, the person's cognitive presence, the person himself.

Another analogy or metaphor might be a **celebration of life**—behaving every day as if every day is a birthday party for the person during which what the person can do is celebrated, not what they can't do. Such a celebration would find the joy of life at every moment *with* dementia. The daily celebration would not include that person's past without dementia just as when we celebrate an older person's actual birthday the celebrants neither focus on what the person used to be able to do when younger nor on all the lost abilities that age has brought.

In fact such celebrations would be filled with cries like: "Life is still now!"

### **Core ethical questions**

Such an approach shines light on one of if not the core ethical question:

"As a consequence of society supporting people with cognitive decline living longer, from a human rights perspective, does society not have the responsibility to provide, support and offer the following opportunities to those with cognitive decline:

- their human rights
- a worthwhile life / a life worth living / a meaningful life
- a normal life
- relationships
- dignity / respect
- opportunity to flourish

Should not everyone living with dementia:

- Expect their definition of "meaningful" to be accepted and embraced
- Be seen as an evolving identity—a new identity which evolves as a result of changing **ecopsychosocial** circumstances
- Deserve the respect for and have a new imperative for self-expression.
- Deserve to develop new interests

- Be able to develop and have a sense of self

Should not everyone living with dementia have?

- “Birthday party ethics” and “graduation ethics” applied to them
- And have their stars celebrated--“celebrate the stars” **(expand on this for sure)**

Take a look again at the problem statement before signing off.