


# Treatment Indications in Clinical Practice and Applied Research on Psychosocial Interventions for People With Dementia

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## Abstract

A recent review of Cochrane meta-analyses on psychosocial interventions (PIs) concludes that clinical trials fail to confirm PIs effective for all types of dementia at every stage of the disease. This article describes how and to what extent it is necessary to identify treatment indications when researching PIs and employing them in clinical practice. Twelve Cochrane reviews on PIs for people with dementia, selected because of their systematic methodology, were searched to identify outcomes related to treatment indications (dosage, type of dementia, severity . . .). The authors identified several research and practice issues that related to treatment indications: sample profiling, hypothesizing and statistical interpretation, external validity, effectiveness of interventions, contraindications and limits of interventions, and tailoring. Developing an effective PI requires empirical, developmental, exploratory, and confirmatory development stages to achieve credibility and robustness.

## Keywords

dementia, psychosocial interventions, evaluation, treatment indications, research, clinical practice, ecopsychosocial

## Introduction

The aim of employing psychosocial interventions (PIs) is to alter the course of a condition that poses significant cognitive, behavioral, emotional, and/or social challenges. Psychosocial interventions are designed to reduce or compensate for these challenges, maintain or enhance abilities and positive emotions, and improve quality of life. Psychosocial interventions use a wide range of resources such as music, sensory stimulation, and social activities to elicit sensory, cognitive, behavioral, and social responses among those targeted for improvement. Zeisel et al<sup>1</sup> suggest that physical environmental design should be included as a PI. These authors propose an *ecopsychosocial* approach in which they conceptually locate PI's in a broader field incorporating environmental and contextual influences of interventions in the lives of those living with dementia. These authors stress that physical design as well as physical contextual factors also need to be investigated to tailor and facilitate implementation of PI's for people with dementia (PwD).

*Treatment indications* in medicine refer to symptoms or particular circumstances that indicate the advisability or necessity of a specific clinical treatment or procedure, including identifying the cause, or some other aspect of a disease (<https://www.nlm.nih.gov/>).<sup>2</sup> Treatment indications relate to a patient's specific biological and/or psychological profile, dosage, adverse effects, and contraindications. They serve an important purpose for clinical practice and must be investigated

thoroughly with robust evaluation procedures in order to apply a clinical treatment without jeopardizing patients' psychological or physiological balance. Treatment indications are rarely identified in studies of PIs.

Vernooij-Dassen and Moniz-Cook<sup>3</sup> point out that because statistical type III errors—also called *implementation errors*—are often found in treatment protocols for PIs in the field of dementia care, PIs often lack precision and reliability, reducing their internal validity that consequently reduces reproducibility and generalizability of PI-related outcomes. Vernooij-Dassen and Moniz-Cook<sup>3(p810)</sup> stress that implementation errors “undermine the credibility of an otherwise successful intervention, thus rendering effect analyses and positive outcomes meaningless [. . .], with associated wasted effort and resources.” They suggest a much needed “paradigm shift in the design and methodology for evaluation of complex interventions in applied dementia care research.”<sup>(p809)</sup> It has not yet

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been proven that PIs are an easy, costless, and harmless alternative compared to pharmacological treatment. In fact, PIs are more epistemologically complex than they are commonly thought to be.

While PIs observably impact the behavior of PwD, meta-analytic reviews of PIs often fail to prove their efficacy for this population with regard to hypothesized effects as defined by the American Psychiatric Association<sup>4</sup>: compensating deficits, maintaining abilities, maintaining positive emotions, and improving quality of life.

Charras et al,<sup>5</sup> in a recent Cochrane meta-analyses review of PIs for PwD, observe that less than a third of reviews show statistically significant results and effects. The authors point out that in order to show any effects of PIs researchers must (1) adapt their investigation methodology to specific characteristics of each PI, (2) acknowledge the methodological weaknesses of randomized control trials (RCTs) that lead to reduced quality of research and clinical practice, (3) apply methodological prerequisites when proceeding to RCTs, and (4) employ research methods other than RCTs that are likely to result in more informative results than RCTs.<sup>6</sup> Charras et al<sup>5</sup> point out that while systematic reviews fail to confirm the overgeneralized statement that PIs are effective for all type of dementia at every stage of the disease, these reviews do not prove that PIs have no effects. The authors observe that such reviews often end with the suggestion that in order to correctly interpret findings and to evaluate effect of PIs, it is necessary to indicate type and severity of dementia. In PI clinical trials, in addition to tailoring interventions to specific populations with dementia, Douglas et al<sup>7</sup> and Woods<sup>8</sup> suggest that there is a need to clearly identify the treatment aims of PIs being studied. Similarly, Van Mierlo et al<sup>9(p802)</sup> state that “little research [has been conducted] into the effects of PIs for subgroups of PwD or their caregivers.” Previous research on PwD by these authors has focused primarily on intrapersonal characteristics on participants and their caregivers who were more sensitive to different types of PIs.<sup>10,11</sup>

The aim of this article is to understand how and to what extent treatment indications are and should be involved with PIs from a research as well as clinical practice perspective. This investigation is a natural progression of Charras et al's<sup>5</sup> study.

## Methods

The Cochrane Database employs a systematic and homogenous methodology across meta-analyses and updates them regularly. For this reason, the PI Cochrane reviews that Charras et al<sup>5</sup> selected in their study, which included finalized reviews referring to PIs for PwD, were also selected in this article. Only most recently updated meta-analytic reviews were included. Studies excluded for this article were protocol descriptions; nonpharmacologic interventions that did not meet the APA definition of PI (2010) such as acupuncture, Transcutaneous Electrical Nerve Stimulation, and whole-body vibration; and PIs focused on caregivers of PwD. Because they were undertaken with objectives that did not fit those of the study, reviews

aimed at determining efficient PIs for only one type or range of symptoms were also excluded.

After verifying that the review author's practice and research conclusions corresponded to the results they indicated, the authors of this study identified and selected the relevant information to the area of concern of this study.

## Results

Employing the Cochrane Library search tool, in August 2014, 176 reviews were identified using the key word “dementia.” Nineteen of these concerned PIs. Seven were excluded: 4 protocols, 2 aimed at determining effectiveness of interventions for a symptom or a range of symptoms, 1 for which the sample was healthy people and people with mild cognitive impairment without mentioning dementia. Unlike Charras et al's study, aromatherapy and light therapy were included in this study, although it is sometimes argued that aromatherapy and light therapy are not PIs because these interventions are based on physiologically invasive essences and processes. Douglas et al<sup>7</sup> point out that these are often considered as PIs and are frequently used in combination with other interventions such as massage, touch, and multisensory interventions. Twelve reviews referring to 13 PIs were ultimately selected: *aromatherapy, cognitive stimulation, cognitive training, cognitive rehabilitation, functional analysis-based interventions, light therapy, massage and touch, music therapy, physical activity, psychological treatments, reminiscence therapy, Snoezelen, and Validation therapy*. For each selected review, Table 1 presents review author quotes that reflect practice and research implications, the concerns of the present study.

## Implications for Research

Analysis of treatment indications in research reveals important methodological questions. Just as Vernooj-Dassen and Moniz-Cook<sup>3</sup> demonstrate that heterogeneity of PI implementation procedures frequently confuses efficacy and effectiveness, analysis of *indications* in the review authors' conclusions, and recommendations (see Table 1) which lead to the same conclusion.

Typical sentences in the research implications of 8 of 12 reviews are “Treatment effects for the different types and severity of dementia need to be investigated” or “future studies should investigate the effect of severity of dementia on treatment efficacy.” Such statements imply that PwD have different personality traits, emotional processing, cognitive functioning, behavioral patterns, and social relations. That must be taken into analytic account. Differential analysis within a comparative approach is necessary to target the range of patient/participant profiles sensitive to a given intervention.

The authors also found that PI reviews that restrict areas of implementation on conceptual grounds (eg, psychological interventions and depression, functional analysis and Behavioral and Psychological Symptoms of Dementia—BPSD, cognitive stimulation, and cognitive deficits) report more robust

**Table 1.** Quotes From Cochrane Meta-Analytic Reviews on PI Referring to Practice and Research Issues Concerning Indications.

Psychosocial Intervention Reviewed by the Cochrane Library (Authors, Year of Last Update)	Definition of the PI and Quotes From the Authors of the Meta-Analyses
Aromatherapy for dementia <sup>12</sup>	<p><i>Definition:</i> Aroma therapy is a part of the discipline of phytotherapy (the use of whole plants or parts of plants for medicinal purposes), and uses pure essential oils from fragrant plants (such as Peppermint, Sweet Marjoram, and Rose) to help relieve health problems and improve quality of life in general.</p> <p><i>Practice:</i> There is plenty of nonrandomized evidence of both benefit and harm for aroma therapy for dementia.</p> <p><i>Research:</i> Treatment effects for the different types and severity of dementia also need to be investigated.</p>
Cognitive stimulation to improve cognitive functioning in people with dementia <sup>8</sup>	<p><i>Definition:</i> Cognitive stimulation is engagement in a range of activities and discussions (usually in a group) aimed at general enhancement of cognitive and social functioning.</p> <p><i>Practice:</i> There is now evidence from a small number of studies that cognitive stimulation may also be associated with improvements in quality of life and communication. [...] consistent with the NICE-SCIE 2006 Guideline recommendation [...] all people with mild to moderate dementia should have the opportunity to participate in cognitive stimulation groups, irrespective of whether or not they are receiving acetylcholinesterase-inhibiting medication (ACHEIs).</p> <p><i>Research:</i> Studying cognitive changes both in relationship to neural processes and pathways; and their linkage, if any, with outcomes such as mood, quality of life, day-to-day function and behaviour. The effects of severity of dementia and different modalities (for example group versus with caregiver) need to be systematically evaluated.</p>
Cognitive training and cognitive rehabilitation for mild to moderate Alzheimer Disease and vascular dementia <sup>13</sup>	<p><i>Definition:</i> Cognitive training is guided practice on a set of standard tasks designed to reflect particular cognitive functions; a range of difficulty levels may be available within the standard set of tasks to suit the individual's level of ability. It may be offered in individual or group sessions, with pencil and paper or computerised exercises.</p> <p><i>Cognitive rehabilitation</i> is an individualised approach where personally relevant goals are identified and the therapist works with the person and his or her family to devise strategies to address these. The emphasis is on improving performance in everyday life rather than on cognitive tests, building on the person's strengths and developing ways of compensating for impairments.</p> <p><i>Practice:</i> Trial reports [cognitive training] indicate that some gains resulting from intervention may not be captured adequately by available standardised outcome measures.</p> <p><i>Research:</i> Future research would benefit from consideration of how to capture changes that are currently missed by the available standardised outcome measures, from development of greater consensus in the selection of specific outcome measures and from identification of the extent to which gains are clinically relevant and generalisable, and have the potential to make a difference for the person with dementia and the family caregiver in everyday life.</p>
Functional analysis-based interventions for challenging behaviour in dementia <sup>14</sup>	<p><i>Definition:</i> Functional analysis is a behavioural intervention that is described by international guidelines as the first line alternative to drug therapy for challenging behaviour.</p> <p><i>Practice:</i> The evidence base for the effectiveness of functional analysis-based interventions continues to rest on randomised controlled trials that incorporate multiple components, leaving the dosage and intensity of functional analysis within the intervention variable and unclear.</p> <p><i>Research:</i> RCTs of functional analysis will require clear treatment protocols that separate caregiver training and support from care plan delivery to the patient, with research designs to measure the relative effects of these on behaviour outcomes. Studies need to also pay attention to clear definitions of: control groups; standardised instruments to measure outcomes on patient behaviour as well as caregiver experience, and time intervals to post-intervention and follow-up.</p>
Light therapy for managing cognitive, sleep, functional, behavioral, or psychiatric disturbances in dementia <sup>15</sup>	<p><i>Definition:</i> Exposure to light to treat symptoms of dementia. The light sources can be: a light box placed approximately one metre away from the participants at a height within their visual fields; a light visor worn on their heads; ceiling mounted light fixtures; or dawn-dusk simulation that mimics outdoor twilight transitions.</p> <p><i>Practice:</i> There is insufficient evidence of the effectiveness of light therapy in managing sleep, functional, behavioural, or psychiatric disturbances associated with dementia.</p> <p><i>Research:</i> Further research is necessary to identify appropriate illumination intensity, frequency, interval, time of day, and length of intervention for individuals with different types and severity of dementia.</p>
Massage and touch for dementia <sup>16</sup>	<p><i>Definition:</i> Massage and touch interventions use sensory stimulation with the aim of counteracting cognitive decline, reducing the frequent accompanying problems of depression, anxiety, aggression and related psychological and behavioural manifestations, improving quality of life, or improving general health and ultimately survival.</p> <p><i>Practice:</i> Some evidence is available to support the efficacy of two specific applications: the use of hand massage for an immediate and short-term reduction of agitated behaviour, and the addition of touch to verbal encouragement to eat for the normalization of nutritional intake.</p> <p><i>Research:</i> Trials should include a well-described randomization procedure, concealed allocation, and a well-defined primary effect parameter.</p>

(continued)

Table I. (continued)

Psychosocial Intervention Reviewed by the Cochrane Library (Authors, Year of Last Update)	Definition of the PI and Quotes From the Authors of the Meta-Analyses
Music therapy for people with dementia <sup>17</sup>	<p><i>Definition:</i> Music therapy is defined as the use of music and/or its musical elements (sound, rhythm, melody, and harmony) by a qualified music therapist, with a client or group, in a process designed to facilitate and promote communication, relationships, learning, mobilisation, expression, organisation and other relevant therapeutic objectives in order to meet physical, emotional, mental, social and cognitive needs [ . . . ]. Two main types of music therapy can be distinguished: receptive and active music therapy.</p> <p><i>Practice:</i> Despite ten studies claiming a favourable effect of music therapy in reducing problems in the behavioural, social, emotional, and cognitive domains in older people with dementia we cannot endorse these claims nor refute any positive effect of music therapy.</p> <p><i>Research:</i> Also more research is needed to differentiate between various music therapy approaches to see if there is a difference between receptive and active music therapy approaches. Further research is also required to compare music therapy provided by mere music listening. In this way, it would be possible to single out the more specific effects of music therapy interventions and methods.</p>
Physical activity programs for persons with dementia <sup>18</sup>	<p><i>Definition:</i> Interventions specifically involving physical activity (aerobic, walk, endurance, or other) in order to increase fitness, physical function, cognition, and positive behaviour.</p> <p><i>Practice:</i> There is insufficient evidence of the effectiveness of physical activity programs on cognition, function, depression behaviour, and mortality in older persons with dementia and on their family caregiver's health, quality of life, and mortality.</p> <p><i>Research:</i> Trials should incorporate: [ . . . ] a more homogeneous sample in terms of diagnosis, severity of disease, and mobility; [ . . . ] a well designed physical activity intervention that is appropriate for people with dementia.</p>
Psychological treatments for depression and anxiety in dementia and mild cognitive impairment <sup>19</sup>	<p><i>Definition:</i> The main psychotherapeutic approaches in treating depression and anxiety in adults, according to the World Health Organization (WHO), are cognitive behavioural therapy, psychodynamic therapy, interpersonal therapy, and supportive counselling (Rogerian person-centred therapy).</p> <p><i>Practice:</i> This review concludes that psychological treatments that primarily target depression and anxiety have the potential to improve psychological well-being for people with dementia.</p> <p><i>Research:</i> Research is also needed into psychological treatments for people with depression and MCI, and to define the effect of the severity of dementia on treatment efficacy.</p>
Reminiscence therapy for dementia <sup>20</sup>	<p><i>Definition:</i> Reminiscence therapy involves the discussion of past activities, events and experiences, with another person or group of people. This is often assisted by aids such as videos, pictures, archives and life story books.</p> <p><i>Practice:</i> It is too early to provide any indication of the effectiveness of reminiscence therapy in comparison with other psychosocial interventions, such as validation therapy or music Therapy.</p> <p><i>Research:</i> The effects of severity of dementia and different modalities (e.g. group versus individual versus with care-giver) need to be systematically evaluated. [ . . . ] The broadening of outcome measures to include well-being, mood and quality of life is welcome, as is a willingness to consider the impact on family and other caregivers.</p>
Snoezelen for dementia <sup>21</sup>	<p><i>Definition:</i> Snoezelen, multisensory stimulation, provides sensory stimuli to stimulate the primary senses of sight, hearing, touch, taste and smell, through the use of lighting effects, tactile surfaces, meditative music and the odour of relaxing essential oils. The rationale for this lies in the proposition that the provision of a sensory environment for people with dementia places fewer demands on their intellectual abilities but capitalizes on their residual sensorimotor abilities.</p> <p><i>Practice:</i> Snoezelen is mainly used as a psychosocial intervention for the management of maladaptive behaviours and promoting mood and communication in people with dementia. In this update, there were no evidences showing the efficacy of snoezelen on behaviours, mood, and interaction of people with dementia. [ . . . ] Without a well-developed evidence-based practice, snoezelen will merely be used as a general programme to occupy people with dementia without a meaningful purpose [ . . . ] there is a need for more reliable and sound research-based evidences to inform and justify the use of snoezelen in dementia care.</p> <p><i>Research:</i> [ . . . ] although existing research provides little information regarding at which stage of dementia (or level of cognitive impairment) clients can benefit most from snoezelen programmes, we are beginning to see reports on the impact of the severity of dementia upon outcomes [ . . . ]. The information is still limited in this respect. [ . . . ] The relationship between the "dose" of the intervention and its outcomes need to be more closely examined. [ . . . ] there is a need to investigate not just the effects of the two forms of snoezelen practice (session-based or integrated approach), but also to examine their similarities and differences as well as comparing their outcomes.</p>

(continued)

**Table 1.** (continued)

Psychosocial Intervention Reviewed by the Cochrane Library (Authors, Year of Last Update)	Definition of the PI and Quotes From the Authors of the Meta-Analyses
Validation therapy for dementia <sup>22</sup>	<p><i>Definition:</i> Validation therapy is based on the general principle of validation, the acceptance of the reality and personal truth of another's experience. The specific interventions and techniques used within the validation approach bring together behavioural and psychotherapeutic methods to meet the needs of individuals with different stages of dementia.</p> <p><i>Practice:</i> [...] there may be some positive behavioural benefits from validation, but there remains insufficient evidence for any benefit from an institutional adoption of validation techniques. [...] The emergence of new approaches that incorporate validation therapy only seek to make decisions about care delivery more complex.</p> <p><i>Research:</i> [...] demonstrate clearly whether any benefits observed can be attributed to the specific nature of the therapy. To date, the randomized studies have focused on a limited range of patient outcomes, and any future research should also seek to evaluate a wider range of participant and caregiver outcomes, including effects on well-being and quality of life, as well as considering the effects on care staff of using this approach.</p>

Abbreviations: PI, psychosocial intervention; RCT, randomized control trial.

evidence compared to those who study a wide range of symptoms or report symptoms not linked to the original purposes of the PI being studied, such as Snoezelen or Validation therapy.

These outcomes highlight important methodological issues in the Cochrane review authors' conclusions: sample profiling, hypothesizing and statistical interpretation, and external validity.

### Implications for Practice

"Insufficient evidence" of effectiveness for prescribing an intervention for PwD is a general conclusion of most of the Cochrane reviews analyzed. Chung et al<sup>21</sup> emphasize the inappropriateness of considering a PI "as a general programme to occupy PwD without a meaningful purpose [...] there is a need for more reliable and sound research-based evidence to inform and justify the use of Snoezelen [*and other psychosocial interventions may we add*] in dementia care" (p11). This observation supports the present authors' conclusion that a single PI cannot address all needs of PwD, but rather only a limited range.

Several reviews suggest that employing a PI with PwD is not without consequences for the person or their relatives. To date, we have failed to prove any harmful effects of PIs; although as Forrester et al<sup>12</sup> stipulate for aromatherapy "there is plenty of nonrandomized evidence of both benefit and harm."

Cochrane review authors' quotes indicate 3 major conceptual issues that treatment indications positively influence in clinical practice: effectiveness, limits and contraindications, and tailoring.

## Discussion

### Implications for Research

*Sampling.* Homogenous sample selection that reflects a particular target of concern may contribute to establishing a causal

relationship between a PI and a related psychological and behavioral target, thus demonstrating the potential impact of the PI on BPSD. On the other hand, a sample drawn from a general PwD population mixes all indications and blurs any mean measured impact.

Suppose, for example, that the overall population of PwD comprises 3 equal-in-size indication segments A, B, and C (subsets of the overall population): with results indicating a positive output for segment A, inefficient output for segment B, and contraindication for segment C. Combining the 3 different impacts will obviously obscure any straightforward conclusion. Even though a slight positive impact may be inferred, since the PI does not apply to segment B and C, results will not reflect the true picture. Statistical results on the impact of the PI efficiency depends entirely on the indication segment of the targeted population.

It is therefore necessary to select research samples with a profile that represents the specific population in need of an intervention. On the other hand, exploratory studies may necessitate samples with a wide range of participant profiles in order to identify those profiles sensitive to an intervention.

When designing a PI, clinicians have in mind characteristics of the PI that will impact the course of the disease, impairment, or disorder. It is logical to assume that PI studies must segment PwD according to those targeted factors (cognitive, emotional, behavioral...) as well as intrinsic factors of participants (age, gender, severity of the disease, symptoms, psychological states, personality traits...) and then set a comparative analysis of impacts of the PI on particular sample segments to determine whether there are any significant impacts.

*Statistical hypothesizing.* The more precise a hypothesized PI effect, the greater the statistical power of results. Preciseness of a hypothesis is highly dependent on accuracy of treatment indications, and conversely treatment indications are refined by sharpening alternative hypotheses. Such circular reasoning

suggests a multi-stage statistical hypothesis testing strategy with exploratory and confirmatory stages requiring more or less precise treatment indications.

In early stages of implementation, referred to in Table 2 as the empirical stage, PI creators and/or experimenters have a vague idea of behavioral, psychological, and social fields that could and are likely to be impacted. Interventions at this stage tend to be conceptually designed to respond to an observed problem in the target population recognized as important by the clinical and scientific community. Such a problem statement can be used to identify intended treatment indications that PI was originally conceptually built to achieve.

Before a PI is subjected to an RCT, its feasibility and range of benefits must be observed in a targeted sample of participants.<sup>3</sup> Experimenters then employ these observations to formulate a broad range of behavioral, psychological, and social impact hypotheses. Such an observational phase is necessary to identify behavioral and psychological characteristics impacted on which more precise hypotheses can be built. The *developmental stage* enables experimenters to test the impact of interventions on originally targeted participants and to identify contraindications and adverse side effects. This phase typically requires *2-tailed hypotheses* in order to establish relationships between potential explanatory variables and outcomes. Results enable investigators to identify possible outcomes and issues related to an intervention and help them monitor and adjust for errors. Allchin<sup>23(p44)</sup> stresses that “in error analytics [ . . . ] controls [randomisation, blinding, control groups . . . ] perform substantive epistemic work by ruling out potential alternatives and thereby deepening reliability.” Only after such an analysis are directional hypotheses and RCTs meaningful. Employing an exploratory perspective in the developmental stages, experimenters better understand both positive and negative relationships between PIs and sets of variables and can test concordance with already tested PIs, theoretical knowledge, and other empirical studies.

Directional causal hypothesis can be formulated in both *exploratory* and *confirmatory research stages*. In exploratory stages, hypotheses will naturally be *2-tailed* whereas in confirmatory stages, depending on the nature of and the expectations for an intervention, hypothesis can also be *1-tailed*.

It is essential to develop hypotheses regarding causal relationships with psychological and social outcome impacts in a targeted participant population for which a PI may provide benefits, excluding those for which the PI is contraindicated. Testing causal hypotheses in this way enables researchers to confirm or deny adverse side effects (disempowerment, risk of failure jeopardizing self-esteem, enhancement of psychotic symptoms) and to determine dosage (duration, periodicity, and frequency) of the intervention according to patient profiles.

A confirmatory study is the best way to test a PI on a specific profile of participants in order to determine its effectiveness within a limited range of dependent variables. Such studies represent a powerful level of proof in traditional medical research, enabling clinicians to practice such that clinical practice and research practice serve each other's interests.

Identifying indications facilitates formulating precise research questions and operationalizing hypotheses which in turn enable researchers to pinpoint indicators closely related to desired primary outcomes. Such choices are less evident in early research stages when concepts are still being developed, inevitably weakening statistical analysis in such studies (see Table 2).

**External validity.** Mayo-Wilson et al<sup>24</sup> claim that taking into account context and participant characteristics helps elucidate causal chains, greatly contributing to external validity and generalizability of outcomes to other settings.

Identifying potential outcomes creates opportunities to implement a PI with people sensitive to it and to optimize implementation conditions. Mayo-Wilson et al<sup>24(p252)</sup> point out that “an intervention that works for one group of people [ . . . ] may not work for people with slightly different problems and comorbidities.”

As discussed earlier, participant profiling is highly dependent on the stage of an intervention's development. It is also essential to determine inclusion and exclusion criteria which are necessary to limit biases from intrapersonal participant characteristics. Reporting adverse effects contributes to identifying an intervention's contraindications and to reduce selection bias. One strategy to explore external validity and determine indications of PIs for PwD is to study their effectiveness for one type or a specific range of dementia symptoms. Several Cochrane Library meta-analytic reviews adopt this approach in an attempt to target PIs that are effective for one type of BPSD.<sup>25,26</sup>

### Implications for Practice

Treatment indications are of primary importance in clinical practice. Clinicians prescribing interventions are trained to pay particular attention to their congruency with specific patient needs and symptomatic profiles.

**Effectiveness of PIs.** Psychosocial interventions with well-defined treatment areas show more robust evidence of effectiveness than PIs claiming to impact a wide range of symptoms and disabilities. Precisely, defining the target population and symptoms for a PI contributes to its internal validity, enabling clinical practitioners to better target a prescribed PI. Mayo-Wilson et al<sup>24(p252)</sup> stress that “lack of information relevant to external validity may prevent practitioners or policy makers from using evidence appropriately to inform decision making, yet existing guidelines do not adequately explain how authors should describe (a) how interventions work, (b) for whom, and (c) under what conditions.”

**Contraindications and limits of PIs.** Whatever helps a person maintain her cognitive, social, emotional, or behavioral functioning and quality of life provides hope to those living with dementia and relatives, creating heightened expectations. Without scientific, conceptual, or empirical evidence, creating such

**Table 2.** Implication of Treatment Indication at Different Stages of Development and Testing of PI.

Stage of Testing	Participant Profile	Theoretical Hypothesizing	Alternative Hypothesis/ Testing	Treatment Indications	Research Implications	Clinical Implications	Examples of Experimental Methods and Designs (Nonexhaustive)	Sample Size
Empirical (efficacy of the intervention)	Broad in the category of intervention (eg, dementia of any type)	Broad suppositions according to the initial objective of the PI	Nondirectional, large confidence intervals (if quantitative data)	Theoretical indication according to the conceptual construct of the PI. No clinical indications can be defined at this stage	Determine the scope of intervention	Observation of impact on single cases	Controlled and repeated observations, interviews, single case studies, and qualitative studies	Small or individual
Developmental (efficacy of the intervention)	Selection of participant profiles that have proven to be more sensitive to the PI	Nondirectional hypothesis on psychological variables that seem more sensitive to the PI	Nondirectional, $P < .05$ , would gain interest if complementary of a correlational approach	Determine treatment contraindications according to participant profile	Understand psychological mechanisms underlying the PI	Explore clinical determinants for implementation and feasibility with defined patients	Testing one or a range of PIs on targeted dementia symptoms, quasi-experimental design	Small
Exploratory (effectiveness of the intervention)	Narrow participant profiles to the desired goals of the PI	Hypothesis according to treatment indications and contraindications	Directional, causal, 2-tailed, $P < .05$	Confirm treatment indications and contraindications	Confirm involved supposed psychological mechanisms underlying the PI	Test frame of intervention on a narrow range of patients, dosage (duration, periodicity, frequency)	RCTs, clinical trials, quasi-experimental designs, natural experimental design, observational studies	Large (sample size calculation)
Confirmatory (effectiveness of the intervention)	Specific participant profile according to the desired goals of the PI	Hypothesis according to desired effect in order to confirm effectiveness of PI	Directional, 2-tailed, or 1-tailed, $P < .05$	Confirm treatment indications for clinical practice	Validation of effects of PI and involved psychological mechanism (may be useful for PI handbooks and manuals)	Confirm treatment indications according to participant profile. Explicit implementation frame (also useful for handbooks)	RCTs	Large (sample size calculation)

Abbreviations: PI, psychosocial intervention; RCT, randomized control trial.

**Table 3.** Practice Recommendations According to Therapeutic or Recreational Intention of Dance Interventions.<sup>28</sup>

Practice Recommendations	Therapeutic Intention	Recreational Intention
Indications	- Motor rehabilitation: walk, gait, balance, and risks of fall; - Cognitive rehabilitation: memory, executive functions, and motor praxis; - Psychological rehabilitation: social interaction, mood, quality of life, social withdrawal, anxiety, depression, agitation	Convivial events, community, regular recreational activity, and social events
Contraindications	Behavior incongruent with treatment intention, severe cognitive disorders, physical health problems, pain, poor mobility, medical advice not to exercise, concurrent major psychiatric disorders, drug, and alcohol abuse	Risk of fall, medical advice not to exercise, fragile health status, drug and alcohol abuse, disruptive behaviors
Participant profiles	Elderly people with dementia or cognitive disorders	Open to anyone
Dosage (period, frequency, and length)	- Period: 12 weeks; - Frequency: at least twice a week; - Length: 30 to 60 minutes (average 40 minutes)	None specified
Session sequencing	(1) Presentation, (2) warm-up, (3) dance practice, (4) freestyle dance, (5) cool down, (6) participant feedback; recommended: break with refreshments	None specified (recommended: warm-up and cool down, break with refreshments)
Setting of intervention	Quiet, relaxing, well-ventilated and spacious room, chairs, and drinks at disposal	Ball room
Observance/attendance	Participant reluctance to attend the sessions should call for reevaluation of appropriateness of intervention	None specified
Contributors and facilitators	Dance teacher, therapist or registered instructor; additional staff to facilitate the session; trained staff if available	Staff, families, friends, etc
Assessment	Cognitive, psychomotor, balance, behavioral	Quality of life, well-being, satisfaction

expectations can appear as miraculous—a promise difficult to keep and thus vulnerable to quackery.

Clinicians administering PIs must be aware of and manage disappointment that can result from failure to treat in response to expectations created, especially when no limits to type and severity of dementia are provided. Woods<sup>27</sup> points out that this phenomenon is most often observed for dementia for which there is little knowledge about symptom progression and for which treatment targets are constantly changing. Establishing clear indications for an intervention will improve clinician's ability to target a specific symptom or sets of symptoms according to the difficulties PwD experience and to focus on symptom-specific evaluations and efficacy of prescribed PI interventions. Relationships between “dosage”—period, frequency, and length—of each intervention and its outcomes must also be evaluated as part of treatment.<sup>14,21</sup> Such a paradigm shift would definitely make it clear to relatives of PwD that when clinicians suggest a PI, they do so with the intention of treating particular disabilities, not to cure the disease.

In practice, clinicians must have evidence—still not available according to the Cochrane Library—that PIs will treat their patients' dementia symptoms. Without scientific evidence, clinicians' hands are tied. Clinicians also require external competences for certain PIs—art therapy for example. They need to know when to suggest a PI even when their own competence does not enable them to treat symptoms directly or when some other PI, for which they do not have deep knowledge, might be indicated. Identifying treatment indications facilitates implementation of complex and tailored interventions.<sup>9</sup>

## Conclusions

The probability is null that a painkiller will prove effective for someone who feels no pain. In most cases, a painkiller will remain harmless if ingested occasionally. But would we nonetheless continue to prescribe this medication or would we bring it to a stop?

The same principle can be applied to psychological and/or PIs for PwD. Based on analysis of Cochrane reviews on effectiveness of PIs for PwD, the authors posit that to prove effectiveness of a PI on PwD, the chosen sample for the implementation must first prove a need for the intervention. In addition, valid statistical analysis will depend on the appropriateness of a study's sampling, statistical hypothesizing, and internal as well as external validity.

Treatment indications for PIs can be defined as valid reasons for prescribing or withholding an intervention in response to symptomatology, needs, targeted deficits, and psychological profiles of PwD. Conclusions from this article, congruent with the *ecopsychosocial* approach,<sup>1</sup> suggest that treatment indications enable clinicians to tailor interventions by specifying dosage (periodicity, frequency, and length) and contextual (physical and social) conditions that will facilitate implementation of a PI according to targeted outcomes. Following this perspective, Mabire et al<sup>28</sup> in a literature review on the effect of dance interventions for PwD suggest breaking down interventions into 10 practice recommendations (Table 3).

Identifying treatment indications and recommendations undoubtedly strengthen research questions and outcomes and also prove more efficient in clinical practice.

Development of a PI necessitates passing through segmented stages in order to gain credibility and robustness. Clinical



trials aim at applying and testing fundamental knowledge to treatment conditions by testing a PI's efficacy and effectiveness in terms of dosage according to specific patient profiles. Following the research stages described in Table 2 will help achieve conditions congruent with Van Mierlo et al's<sup>9</sup> 16 core components of personalized care in order to tailor interventions to individual needs and symptomatic profiles. It is of the responsibility of both clinicians and researchers to insure the reliability of PI treatments. One cannot proceed without the other, and whatever recognition a PI has from the clinical and scientific community, it must always be further investigated in order to guarantee its effectiveness and seriousness.

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