

Non-pharm (behavioral, eco-biopsychosocial) interventions for delirium: Challenges & issues

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Objectives

- Review background & recent work in non-pharm
- Single versus multi-component with examples
- Methodological Issues
- Fidelity
- Gaps and Novel Questions

orientation strategies	vision and hearing aids	sleep environment
family participation	uncluttered hallways	multimodal pain control
remove urinary catheters and other tethers	WHAT IS GOOD FOR DELIRIUM, IS GOOD FOR FALLS, IS GOOD FOR FUNCTIONAL DECLINE.	wound care: minimize pressure, friction, humidity, shear force
avoid potentially inappropriate medications		resume diet early and provide dentures, if needed
chest physiotherapy and incentive spirometry	early, multidisciplinary involvement	nutritional supplement, if needed
early mobilization, using walking aids if needed	scheduled toileting	aspiration precautions

Non-pharm--What exactly is it and what do we know about it?

- **THE EVIDENCE**—we need more evidence in this area. Studies are often under powered, have high bias from lack of methodological rigor or lack fidelity, more single RCT's
- **"A ROSE BY ANY OTHER NAME"** The field is moving AWAY from the name non-pharm as it puts the emphasis on DRUGS-where actually that should always be the LAST RESORT and often leads to more harm or worsening delirium (as we will show in a minute) and it does not reflect what we do!

BASIS of Approaches (early work)

The New England Journal of Medicine

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VOLUME 340

MARCH 4, 1999

NUMBER 9



A MULTICOMPONENT INTERVENTION TO PREVENT DELIRIUM IN HOSPITALIZED OLDER PATIENTS

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ABSTRACT

Background Since in hospitalized older patients delirium is associated with poor outcomes, we evaluated the effectiveness of a multicomponent strategy for the prevention of delirium.

Methods We studied 852 patients 70 years of age or older who had been admitted to the general-medicine service at a teaching hospital. Patients from one intervention unit and two usual-care units were enrolled by means of a prospective matching strategy. The intervention consisted of standardized protocols for the management of six risk factors for delirium: cognitive impairment, sleep deprivation, immobility, visual impairment, hearing impairment, and dehydration. Delirium, the primary outcome, was assessed daily until discharge.

Results Delirium developed in 9.9 percent of the intervention group, as compared with 15.0 percent of

DELIRIUM, also known as acute confusional state, is a common, serious, and potentially preventable source of morbidity and mortality among hospitalized older patients.¹⁻³ Delirium has particular importance because patients over 65 years of age account for more than 48 percent of all days of hospital care.⁴ Each year, delirium complicates hospital stays for more than 2.3 million older people, involves more than 17.5 million inpatient days, and accounts for more than \$4 billion (in 1994 dollars) of Medicare expenditures.⁵ Substantial additional costs accrue after discharge from the hospital, because of the increased need for institutionalization, rehabilitation, and home care.^{6,7} Moreover, the incidence of delirium will probably increase with the aging of the population.⁸

Previous interventional studies of delirium have fo-

Number of Non-Drug Studies Increasing

- HELP cluster RCT Surgery patients Chen et al., 2017 JAMA Surgery
- RESERVE paper Kolanowski et al., Cognitive Stimulation JAGS
- JAGS drugs paper Review, Neufeld et al., 2017
- Waszynski et al 2017, Int Jnl Nursing Studies-Simulated Family Presence
- Hsieh et al., 2015 JAMA Meta-Analysis Prevention
- JAMA review by Oh and Colleagues, 2017
- NEJM paper Marcantonio, October 12, 2017
- Eeles et al, 2017 Australas J Agin Real-world solutions

Antipsychotic Medication for Prevention and Treatment of Delirium in Hospitalized Adults: A Systematic Review and Meta-Analysis

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Sharon K. Inouye, MD, MPH,^{**†‡b} and Dale M. Needham, MD, PhD^{†‡b}

OBJECTIVES: To evaluate the effectiveness of antipsychotic medications in preventing and treating delirium.

DESIGN: Systematic review and meta-analysis.

SETTING: PubMed, EMBASE, CINAHL, and ClinicalTrials.gov databases were searched from January 1, 1988, to November 26, 2013.

PARTICIPANTS: Adult surgical and medical inpatients.

INTERVENTION: Antipsychotic administration for delirium prevention or treatment in randomized controlled trials or cohort studies.

MEASUREMENTS: Two authors independently reviewed all citations, extracted relevant data, and assessed studies for potential bias. Heterogeneity was considered as chi-square $P < .1$ or $I^2 > 50\%$. Using a random-effects model ($I^2 > 50\%$) or a fixed-effects model ($I^2 < 50\%$), odds ratios (ORs) were calculated for dichotomous outcomes (delirium incidence and mortality), and mean or standardized mean difference for continuous outcomes (delirium duration, severity, hospital and intensive care unit (ICU)

with high risk of bias, and typical versus atypical antipsychotics.

RESULTS: Screening of 10,877 eligible records identified 19 studies. In seven studies comparing antipsychotics with placebo or no treatment for delirium prevention after surgery, there was no significant effect on delirium incidence (OR = 0.56, 95% confidence interval (CI) = 0.23–1.34, $I^2 = 93\%$). Using data reported from all 19 studies, antipsychotic use was not associated with change in delirium duration, severity, or hospital or ICU LOS, with high heterogeneity among studies. No association with mortality was detected (OR = 0.90, 95% CI = 0.62–1.29, $I^2 = 0\%$).

CONCLUSION: Current evidence does not support the use of antipsychotics for prevention or treatment of delirium. Additional methodologically rigorous studies using standardized outcome measures are needed. *J Am Geriatr Soc* 64:705–714, 2016.

Key words: delirium; pharmacological prevention; pharmacological treatment; adult

Original Investigation | HEALTH CARE REFORM

Effectiveness of Multicomponent Nonpharmacological Delirium Interventions

A Meta-analysis

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IMPORTANCE Delirium, an acute disorder with high morbidity and mortality, is often preventable through multicomponent nonpharmacological strategies. The efficacy of these strategies for preventing subsequent adverse outcomes has been limited to small studies to date.

OBJECTIVE To evaluate available evidence on multicomponent nonpharmacological delirium interventions in reducing incident delirium and preventing poor outcomes associated with delirium.

DATA SOURCES PubMed, Google Scholar, ScienceDirect, and the Cochrane Database of Systematic Reviews from January 1, 1999, to December 31, 2013.

STUDY SELECTION Studies examining the following outcomes were included: delirium incidence, falls, length of stay, rate of discharge to a long-term care institution (institutionalization), and change in functional or cognitive status.

DATA EXTRACTION AND SYNTHESIS Two experienced physician reviewers independently and blindly abstracted data on outcome measures using a standardized approach. The reviewers conducted quality ratings based on the Cochrane risk-of-bias criteria for each study.

MAIN OUTCOMES AND MEASURES We identified 14 interventional studies. The results for outcomes of delirium incidence, falls, length of stay, and institutionalization were pooled for the meta-analysis, but heterogeneity limited our meta-analysis of the results for change in functional or cognitive status. Overall, 11 studies demonstrated significant reductions in delirium incidence (odds ratio [OR], 0.47; 95% CI, 0.38-0.58). Four randomized or matched trials reduced delirium incidence by 44% (OR, 0.56; 95% CI, 0.42-0.76). The rate of falls decreased significantly among intervention patients in 4 studies (OR, 0.38; 95% CI, 0.25-0.60); in 2 randomized or matched trials, the rate of falls was reduced by 64% (OR, 0.36; 95% CI, 0.22-0.61). Length of stay and institutionalization also trended toward decreases in the intervention groups, with a mean difference of -0.16 (95% CI, -0.97 to 0.64) day shorter and the odds of institutionalization 5% lower (OR, 0.95; 95% CI, 0.71-1.26). Among higher-quality randomized or matched trials, length of stay trended -0.33 (95% CI, -1.38 to 0.72) day shorter, and the odds of institutionalization trended 6% lower (OR, 0.94; 95% CI, 0.69-1.30).

CONCLUSIONS AND RELEVANCE Multicomponent nonpharmacological delirium prevention interventions are effective in reducing delirium incidence and preventing falls, with a trend toward decreasing length of stay and avoiding institutionalization. Given the current focus on prevention of hospital-based complications and improved cost-effectiveness of care, this meta-analysis supports the use of these interventions to advance acute care for older

JAMA Int Med 2015

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**11/14 STUDIES
DECREASED
DELIRIUM
INCIDENCE (OR
0.47)**

**2 RCTs
FALLS 64%**



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JAMA | Review

Delirium in Older Persons

Advances in Diagnosis and Treatment

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IMPORTANCE Delirium is defined as an acute disorder of attention and cognition. It is a common, serious, and often fatal condition among older patients. Although often underrecognized, delirium has serious adverse effects on the individual's function and quality of life, as well as broad societal effects with substantial health care costs.


OBJECTIVE To summarize the current state of the art in diagnosis and treatment of delirium and to highlight critical areas for future research to advance the field.

EVIDENCE REVIEW Search of Ovid MEDLINE, Embase, and the Cochrane Library for the past 6 years, from January 1, 2011, until March 16, 2017, using a combination of controlled vocabulary and keyword terms. Since delirium is more prevalent in older adults, the focus was on studies in elderly populations; studies based solely in the intensive care unit (ICU) and non-English-language articles were excluded.

FINDINGS Of 127 articles included, 25 were clinical trials, 42 cohort studies, 5 systematic reviews and meta-analyses, and 55 were other categories. A total of 11 616 patients were represented in the treatment studies. Advances in diagnosis have included the development of brief screening tools with high sensitivity and specificity, such as the 3-Minute Diagnostic Assessment; 4 A's Test; and proxy-based measures such as the Family Confusion Assessment Method. Measures of severity, such as the Confusion Assessment Method–Severity Score, can aid in monitoring response to treatment, risk stratification, and assessing prognosis. Nonpharmacologic approaches focused on risk factors such as immobility, functional decline, visual or hearing impairment, dehydration, and sleep deprivation are effective for delirium prevention and also are recommended for delirium treatment. Current recommendations for pharmacologic treatment of delirium, based on recent reviews of the evidence, recommend reserving use of antipsychotics and other sedating medications for treatment of severe agitation that poses risk

 [Author Audio Interview](#)

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 [CME Quiz at
jamanetwork.com/learning](#)

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Table 4. Multicomponent Nonpharmacologic Approaches to Delirium Prevention

Approach	Description
Orientation and therapeutic activities	Provide lighting, signs, calendars, clocks Reorient the patient to time, place, person, your role Introduce cognitively stimulating activities (eg, reminiscing) Facilitate regular visits from family, friends
Fluid repletion	Encourage patients to drink; consider parenteral fluids if necessary Seek advice regarding fluid balance in patients with comorbidities (heart failure, renal disease)
Early mobilization	Encourage early postoperative mobilization, regular ambulation Keep walking aids (canes, walkers) nearby at all times Encourage all patients to engage in active, range-of-motion exercises
Feeding assistance	Follow general nutrition guidelines and seek advice from dietician as needed Ensure proper fit of dentures
Vision and hearing	Resolve reversible cause of the impairment Ensure working hearing and visual aids are available and used by patients who need them
Sleep enhancement	Avoid medical or nursing procedures during sleep if possible Schedule medications to avoid disturbing sleep Reduce noise at night
Infection prevention	Look for and treat infections Avoid unnecessary catheterization Implement infection-control procedures
Pain management	Assess for pain, especially in patients with communication difficulties Begin and monitor pain management in patients with known or suspected pain
Hypoxia protocol	Assess for hypoxia and oxygen saturation
Psychoactive medication protocol	Review medication list for both types and number of medications

Prevention

Multicomponent Nonpharmacologic Interventions

Primary prevention with multicomponent nonpharmacologic approaches has been consistently demonstrated to be the most effective strategy for delirium prevention among hospitalized, non-ICU medical and surgical patients. These prevention strategies include early mobilization, adequate hydration, sleep enhancement, orientation to time and place, therapeutic activities such as reminiscence (for cognitive stimulation), and hearing and vision optimization by using hearing and vision aids as needed. Table 4 provides details on these specific approaches to guide clinicians in how to implement delirium prevention strategies.

Because delirium is usually precipitated by multiple factors, effective prevention strategies should be implemented together (typically 3 or more at a time) by a multidisciplinary team. In a meta-analysis of 14 interventional studies based on the Hospital Elder Life Program,^{57,58} these approaches significantly reduced the risk of incident delirium by 53% (odds ratio, 0.47 [95% CI, 0.38-0.58]), and the risk of falls by 62% (odds ratio, 0.38 [95% CI, 0.25-0.60]) among hospitalized, non-ICU patients 65 years and older.²²

Multicomponent nonpharmacologic approaches are cost-effective, with 1 study demonstrating an incremental net monetary benefit of £8180 (US \$12 852 in 2014), using a cost-effectiveness threshold of £20 000 (US \$31 423) per quality-adjusted life year.⁵⁹ This study took the novel approach of statistical modeling for patients undergoing surgical hip fracture repair, using decision tree analysis to explore deterministic and probabilistic sensitivity analyses. A Cochrane review of delirium prevention examined 39 trials involving 16 082 patients⁶⁰ and found moderate-quality evidence that multicomponent nonpharmacologic interventions are effective for prevention of incident delirium but less robust for decreasing delirium severity or duration.⁶⁰ Educating nursing aides and

Multi-Component Versus Single

- Evidence from both delirium and dementia studies and systematic reviews show that a combination approach may be more potent
- Delirium is often multi-causal
- Single component cleaner (fidelity and rigor) and easier to say it worked or did not work
- Multi-component approach not always realistic in the real world of practice—practice setting--picking top 3-4 approaches without evidence

NIH Delirium Trials at PSU <http://clinicaltrials.gov/>

RESERVE

- Focus on DSD
- RCT Intervention
- SINGLE Component
- Post-acute Care
- Patient Centered

END-DSD

- Focus on DSD
- C-RCT Intervention
- MULTI-Dimensional
- Acute Hospitalization
- Nurse & Pt Centered

Effect of Cognitively Stimulating Activities on Symptom Management of Delirium Superimposed on Dementia: A Randomized Controlled Trial

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“Did not improve delirium free days, but improved executive function & LOS”

OBJECTIVE: To determine whether cognitively stimulating activities would reduce duration and severity of delirium and improve cognitive and physical function to a greater extent than usual care.

DESIGN: Single-blind randomized clinical trial.

SETTING: Eight post-acute care (PAC) facilities.

PARTICIPANTS: Community-dwelling older adults with dementia and delirium (N = 283).

INTERVENTION: Research staff provided cognitively stimulating activities daily for up to 30 days.

MEASUREMENTS: Primary outcomes were delirium

95% CI = 5.45–6.33; difference –0.69, 95% CI = 1.33 to –0.06, $P = .03$; constructional praxis (range 0–15): intervention: 8.84, 95% CI = 8.83–9.34; control: 7.53, 95% CI = 7.04–8.01; difference –1.31, 95% CI = 2.01 to –0.61, $P < .001$). After adjusting for baseline constructional praxis, the group comparison was no longer significant. Average length of stay was shorter in the intervention (36.09 days) than the control (53.13 days) group (standard error = 0.15, $P = .01$, negative binomial regression).

CONCLUSION: Cognitively stimulating activities did not improve delirium but improved executive function and reduced length of stay. Resolution of delirium may require more-intense nonpharmacological management when the

Effect of a Modified Hospital Elder Life Program on Delirium and Length of Hospital Stay in Patients Undergoing Abdominal Surgery A Cluster Randomized Clinical Trial

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IMPORTANCE Older patients undergoing abdominal surgery commonly experience preventable delirium, which extends their hospital length of stay (LOS).

OBJECTIVE To examine whether a modified Hospital Elder Life Program (mHELP) reduces incident delirium and LOS in older patients undergoing abdominal surgery.

DESIGN, SETTING, AND PARTICIPANTS This cluster randomized clinical trial of 577 eligible patients enrolled 377 older patients (≥ 65 years of age) undergoing gastrectomy, pancreaticoduodenectomy, and colectomy at a 2000-bed urban medical center in Taipei, Taiwan, from August 1, 2009, through October 31, 2012. Consecutive older patients scheduled for elective abdominal surgery with expected LOS longer than 6 days were enrolled, with a recruitment rate of 65.3%. Participants were cluster randomized by room to receive the mHELP or usual care.

INTERVENTIONS The intervention (implemented by an mHELP nurse) consisted of 3 protocols administered daily: orienting communication, oral and nutritional assistance, and early mobilization. Intervention group participants received all 3 mHELP protocols postoperatively, in addition to usual care, as soon as they arrived in the inpatient ward and until hospital discharge. Adherence to protocols was tracked daily.

MAIN OUTCOMES AND MEASURES Presence of delirium was assessed daily by 2 trained nurses who were masked to intervention status by using the Confusion Assessment Method. Data on LOS were abstracted from the medical record.

RESULTS Of 577 eligible patients, 377 (65.3%) were enrolled and randomly assigned to the mHELP ($n = 197$; mean [SD] age, 74.3 [5.8] years; 111 [56.4%] male) or control ($n = 180$; mean [SD] age, 74.8 [6.0] years; 103 [57.2%] male) group. Postoperative delirium occurred in 13 of 196 (6.6%) mHELP participants vs 27 of 179 (15.1%) control individuals, representing a relative risk of 0.44 in the mHELP group (95% CI, 0.23–0.83; $P = .008$). Intervention group participants received the mHELP for a median of 7 days (interquartile range, 6–10 days) and had a shorter median LOS (12.0 days) than control participants (14.0 days) ($P = .04$).

CONCLUSIONS AND RELEVANCE For older patients undergoing abdominal surgery who received the mHELP, the odds of delirium were reduced by 56% and LOS was reduced by 2 days. Our findings support using the mHELP to advance postoperative care for older patients undergoing major abdominal surgery.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT01045330.

JAMA Surg. 2017;152(9):827–834. doi:10.1001/jamasurg.2017.1083
Published online May 24, 2017.

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 Supplemental content

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- CLUSTER RCT-2 WARDS
- N=377
- Decreased both delirium (6.6% vs 15.1%) and LOS
- mHELP (modified) program targeting just 3 protocols-orienting communication, oral/nutritional, & mobility
- Delivered by trained nurses

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Methodological Issues to Address

- Premise and underlying mechanism
- *Pilot testing*
- *Fidelity*
- *Dosage/strength*
- Duration
- Blinding
- *Training and standardization for intervention/who does TX*
- Practical start up issues-site agreements, multiple IRB's

Doing a PILOT STUDY is CRITICAL

- Even if it is just 5 people (I did 15 for my first R01 & 16 for 2nd R01 and published both)
- Pilot as many components as possible to look for PITFALLS
- Establishes feasibility
- Relationships, agreements and LOS with sites
- Recruitment
- IRB
- Beginning of procedures manuals, training materials
- WHAT WORKS/what needs to be changed



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Why Care About Treatment Fidelity?

- Integrity of your study
- Tells you if treatment was delivered as intended
- Impacts study validity
- If fidelity not monitored & optimized and positive results-then do not know if the treatment is an effective treatment or unknown factors
- Helps with implementation and translating into practice

Treatment Fidelity Issues In Design

- Ensure same treatment dose (number, frequency & length of contact) within conditions (delirium example from RESERVE study, 2016)
- Ensure equivalent dose across conditions or sites
- Plan for implementation setbacks-track attrition, have a pool of providers, have both computer and human training available

Table 2
Treatment Fidelity Strategies for Monitoring and Improving Provider Training

Goal	Description	Strategies
Standardize training.	Ensure that training is conducted similarly for different providers.	Ensure that providers meet a priori performance criteria; have providers train together; use standardized training manuals/materials/provider resources/field guides; have training take into account the different experience levels of providers; use structured practice and role-playing; use standardized patients; observe intervention implementation with pilot participants; use same instructors for all providers; videotape training in case there needs to be future training for other providers; design training to allow for diverse implementation styles.
Ensure provider skill acquisition.	Train providers to well-defined performance criteria.	Observe intervention implementation with standardized patients and/or pilot participants (role-playing); score provider adherence according to an a priori checklist; conduct provider-identified problem solving and debriefing; provide written exam pre- and posttraining; certify interventionists initially (before the intervention) and periodically (during intervention implementation).
Minimize "drift" in provider skills.	Ensure that provider skills do not decay over time (e.g., show that provider skills demonstrated halfway through the intervention period are not significantly different than skills immediately after initial training).	Conduct regular booster sessions; conduct in vivo observation or recorded (audio- or videotaped) encounters and review (score providers on their adherence using a priori checklist); provide multiple training sessions; conduct weekly supervision or periodic meetings with providers; allow providers easy access to project staff for questions about the intervention; have providers complete self-report questionnaire; conduct patient exit interviews to assess whether certain treatment components were delivered.
Accommodate provider differences.	Ensure adequate level of training in layperson providers or providers of differing skill level, experience or professional background.	Have professional leaders supervise lay group leaders/paraprofessionals; monitor differential drop-out rates; evaluate differential effectiveness by professional experience; give all providers intensive training; use regular debriefing meetings; use provider-centered training according to needs, background, or clinical experience; have inexperienced providers add to training by attending workshops or training programs.

Fidelity Plan Example-Kolanowski et al., 2006-Amer Jnl Alz Dis & Other Dem

Appendix D Treatment Fidelity Check

Subject Code: _____ Facility: _____
Date: _____ Time: _____
Interventionist: _____

At the completion of each activity session, please evaluate the extent to which the activity was implemented by answering the following questions:

Was today's activity the one selected for this condition?

Yes _____

No _____

Explain:

Were there any extraneous circumstances that influenced the delivery of the activity?

_____ a. Inability to form group activity.

Explain:

_____ b. Inability of subject to stay by himself or herself for independent activity.

Explain:

(continued)

Other Methodological Tips

- Design with implementation in mind
- AMC's versus community-pros and cons
- Cost-what (optimize) and who does the tx (involve a health economist)
- Testing across types of severity of impairment and in dementia types

Lessons from October 2017 NIH Summit on Dementia Research and Care

- CO-DESIGN-hearing from persons with the condition
- LANGUAGE
- INDIVIDUALIZED & PERSON-CENTERED
- Removing academic jargon and making research relevant
- RCT's combining activities-physical/cognitive/more engaging
- HOMECARE as the missing link with improved outcomes
- CHALLENGES & ethics of balancing relevance, co-design and rigor

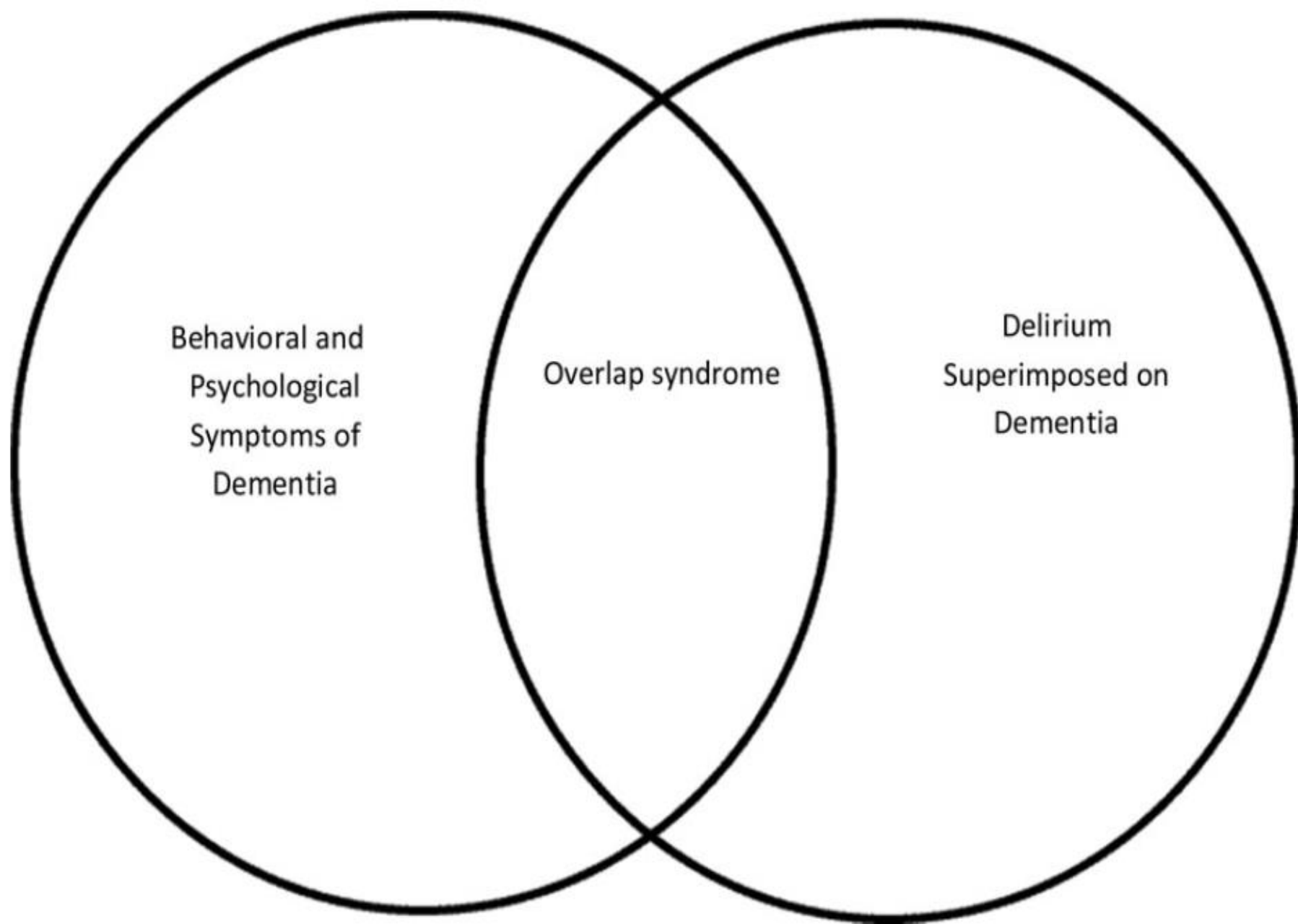


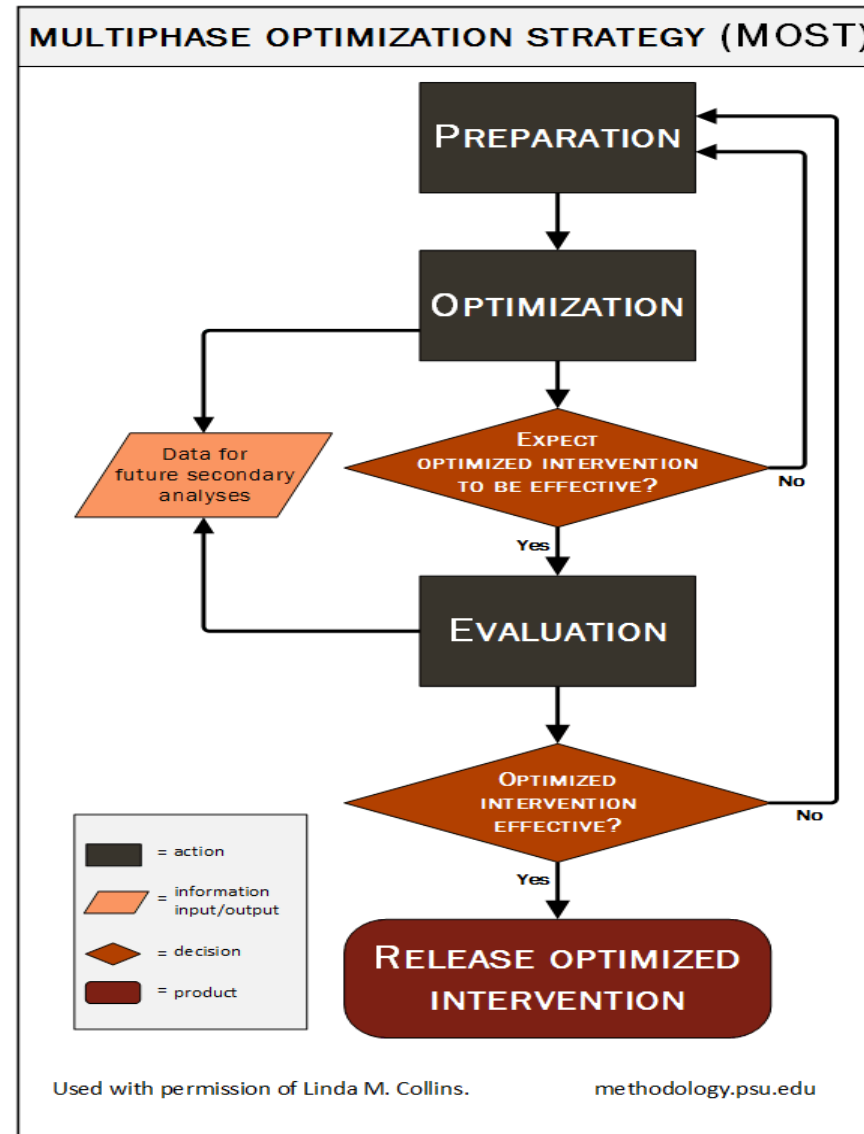
Figure 2. Diagrammatic representation of the relationship between BPSD and DSD. There is some overlap in the symptoms of BPSD and delirium and it is possible that in fact what is attributed to BPSD in research and clinical practice is actually DSD

GAPS IN INTERVENTION RESEARCH

- Outcomes more distal to delirium
- Conducting interventions in community and transitional care
- Novel methods-mixed methods, MOST, SMART DESIGNS
- Capturing impact of multiple chronic conditions
- Involving stakeholders-clinicians, caregivers, persons with impairment

The goal may be to develop a cost-effective intervention, an intervention that achieves a specified level of effectiveness, the briefest intervention that achieves a minimum level of effectiveness, or any other reasonable and explicitly operationalized goal. <https://methodology.psu.edu/ra/most/research>

Figure 1.



Novel Research Questions

- Technology based
- Co-design
- Setting-Home/Community/LTC and Assisted Living
- Head to head trials with non-pharm and drugs
- Special populations (living alone, intellectual disabilities, dementia, children, surgical)

BOTH A GAP AND OPPORTUNITY IN LTC & HOMECARE

- Transfers to acute care from LTC
- Caregiver support AND HOME HEALTH/COMMUNITY
- Technology—Steis et al., 2012 Online Journal of Nursing Informatics
- Voyer, P., Champoux, N., Desrosiers, J., Landreville, P., McCusker, J., Monette, J., Savoie, M., Richard, S., Carmichael, P.H. (2015). Recognizing Acute Delirium As part of your Routine [RADAR]: A validation study. BMC Nursing, 14:19.
- <http://www.biomedcentral.com/1472-6955/14/19>

Recommendations

- PILOT, PILOT, PILOT
- PAY ATTENTION TO PRACTICAL ASPECTS
- PAY ATTENTION TO FIDELITY & FEASIBILITY
- THINK ABOUT AREAS & SETTINGS WHERE WE HAVE GAPS IN THE EVIDENCE
- CONSIDER NOVEL APPROACHES & METHODS-MIXED METHODS, MOST

References/citations-email
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