

Dementia Methods Pre-Summit Materials

Session 4

Study Design and Implementation: Testing Interventions for People with Dementia and their Families

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Methodologic Approaches to Dementia Research

Research Design	Description	Advantages	Disadvantages	Examples of use
Methods				
Qualitative methods	Qualitative research focuses on social and interpreted, rather than quantifiable, phenomena and aims to discover, interpret, and describe rather than to test and evaluate. Qualitative research makes inductive, descriptive inferences to theory concerning social experiences or settings, whereas quantitative research makes causal or correlational inferences to populations. Qualitative research is not a single method but a family of analytic approaches that rely on the description and interpretation of qualitative data. Specific methods include, for example, grounded theory, ethnography, phenomenology, case study, critical theory, and historiography.	Inductive approach through interviews More flexibility in data collection than in quantitative research Smaller sample size Source: (Alzheimer's Europe 2009)	From (Alzheimer's Europe 2009): No pre-determined hypotheses No statistical analyses Source: (Alzheimer's Europe 2009)	(see randomized clinical, observational)
Quantitative methods	The investigation of phenomena that lend themselves to test well-specified hypotheses through precise measurement and quantification of predetermined variables that yield numbers suitable for statistical analysis.	Deductive approach Built on hypothesis testing Precise pre-determined measurement of variables Critical assessment of bias Control for external factors Statistical analysis of associations or causal relationships Source: (Alzheimer's Europe 2009)	Findings that are not statistically significant not considered positive outcome Source: (Alzheimer's Europe 2009)	Experiences with provision of care: Interviews and videotapes with 27 people with dementia living in residential and day care settings, along with 28 relatives were also interviewed. Themes were coded based on verbal and non-verbal responses based on individualized approach to interviews (Aggarwal 2003)

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Mixed methods	Pragmatic approach bridging quantitative and qualitative methods, using the method which appears best suited to the research problem	Use of triangulation Ability to use quantitative or qualitative techniques simultaneously or consecutively Source: (Alzheimer's Europe 2009)	Conducting analysis and determining results with two different types of data Significant time commitment from research team Source: (Alzheimer's Europe 2009)	Intergenerational volunteering: Participant-observation evaluation of an RCT assessing impact of volunteering with children 5-14 years on patients with dementia. Unstructured interviews assessed alongside statistical analysis of psychometric test change scores on cognitive functioning, stress, depression, sense of purposeness and usefulness, given at baseline and post-intervention. (George 2011)
Design				
Randomized	A study in which randomization is used to assign study subjects to interventions and which can range in the amount of control exercised by the investigators.	Randomized assignment Controlled environment	Small sample Not necessarily generalizable to usual care Ethical restraints Central tendency	(see stratified randomized, randomized clinical trial)
Stratified randomized	A randomized trial that assigns subjects to blocks of covariates prior to randomization.	Randomized assignment Control influence of baseline characteristics	As in Randomized	Occupational therapy: Randomized allocation of dementia patients to 10 sessions of occupational therapy at home over 5 weeks or no therapy. Patients stratified by severity of dementia and tested at baseline, 6 weeks and 12 weeks; assessing daily motor and process skills in patients and sense of competence in caregivers. (Graff 2006)

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Non-randomized	A study that does not use randomization to assign participants to intervention arms.	Does not require blind allocation Greater applicability and potential generalizability than in strict standardized settings Less expensive than randomized trials Source: (Cohen-Mansfield 2012)	As in Observational	Adult-day services: Use of an adult-day service for patients with dementia and their caregivers, recruited from adult day centers (for treatment group) and respits agencies (for control group). Interviews were conducted at 3-month intervals with caregivers to report daily record of behavior. Testing ADL dependency, cognitive functioning, daily record of behavior between treatment and control groups. (Femia 2007)
Observational	Study in which individuals are observed or certain outcomes are measured. No attempt is made to affect the outcome (for example, no treatment is given).	Does not require blind allocation Greater applicability and potential generalizability than in strict standardized settings Less expensive than randomized trials Source: (Cohen-Mansfield 2012)	Selection bias Measurement imprecision Confounding Determining within-person change given aging and cognitive decline. Source: (Weuve 2015)	(see case-control, cohort, cross-sectional)
Case-control	Nonrandomized study of patients with a specific outcome (cases) compared to patients without the outcome (controls).	as in Observational	as in Observational	Animal-Assisted therapy: patients with dementia (N=75) residing in 18 nursing homes in Germany with a sum score on the MMSE of 25 or greater. Animal-assisted therapy provided to 35 subjects with 40 subjects assigned to control and evaluated on agitation and depressive symptoms using the CMAI and DMAS. (Majic 2013)

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Cohort	<p>Prospective: Nonrandomized study of a group of patients with a common condition or exposure over time where data are collected prospectively (after the start of the trial).</p> <p>Retrospective: Nonrandomized study of a group of patients with a common condition or exposure over time where data are collected retrospectively, i.e. from a secondary data source.</p>	as in Observational	as in Observational + no unexposed (control) group	Multi-component therapy: Prospective cohort of 104 men with dementia living in 2 veterans homes in Taiwan. A program of music therapy, orientation training, art-cognitive activities and physical activities were provided. Depressive symptoms, ADLs, MMSE, use of psychotropic drugs, gait were evaluated. (Chen 2013)
Cross-sectional	Study in which the presence or absence of disease or other health-related variables are determined in each member of the study population or in a representative sample at one particular time.	as in Observational	as in Observational + no exposure over time	Care needs in residential care: A survey conducted at 10 residential homes in the Netherlands, evaluating care needs using the Camberwell Assessment of Need in the Elderly (CANE) for patients with dementia (N=62) and those without dementia (N=89). (van der Ploeg 2013)
Natural experiment				(none found)
Interventional				
Adaptive trial	A trial that uses information that accumulates during the course of the trial as well as prior information to decide how to modify aspects of the trial as it continues.			(none found)

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Randomized clinical trial	A study in which randomization is used to assign study subjects to interventions and which can range in the amount of control exercised by the investigators. Randomized controlled trials determine whether a clinical intervention is effective under optimal circumstances. This is achieved by using rigorous inclusion and exclusion criteria and a highly controlled research environment. Pragmatic randomized studies determine the harms, benefits, and costs of an intervention as it would occur in routine clinical practice. This is achieved by including a combination of a broader range of subjects, study sites, and outcomes.	As in Randomized	Challenges with consent in subjects with cognitive impairment Expensive/cost-prohibitive Requires robust power to detect differences May not be representative of community Source: (Ritchie 2015)	Theory-based activities: three phase intention-to-treat RCT. participants were randomized into one of four groups: activities tailored to functional level (n= 32); activities tailored to personality style of interest (n= 33); activities tailored to both functional level and personality style of interest (n= 31); and active control (n= 32). Agitation, passivity, engagement, affect and mood measured. (Kolanowski 2011)
Cluster randomized trial	A randomized clinical trial that groups subjects according to "clusters," such as clinic site or community. Randomization is used to assign entire clusters to interventions. This design is useful when evaluating health policies or when randomization at the subject level is possible.	As in Randomized + eliminates need for subject randomization	Challenges with consent in subjects with cognitive impairment Expensive/cost-prohibitive Requires robust power to detect differences May not be representative of community Source: (Ritchie 2015)	Humor therapy: Cluster randomized trial (N=35 nursing homes) evaluating improvements in agitation, behavioral disturbances and depressive symptoms (Low 2013)

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Crossover randomized trial		As in Randomized + each subject experiences all trial arms	Challenges with consent in subjects with cognitive impairment Expensive/cost-prohibitive Requires robust power to detect differences May not be representative of community Source: (Ritchie 2015)	Montessori education: Crossover randomized trial (N=44) evaluating improvements in behavior after 4 weeks of Montessori education and 4 control blocks (van der Ploeg 2012)
Interrupted time series trial	The interrupted time-series design provides an estimate of the causal effect of a discrete intervention. In its simplest form, the design begins from a long series of repeated measurements on a dependent variable. The intervention breaks this time series into preintervention and postintervention segments, and a data analysis compares the means of the dependent variable in the two periods.			Nutrition assistance: Multiple-phase study in 98 dementia patient hospitalized in short stay units in New Zealand. Observation phase, encouraging dietary grazing phase, using volunteers to feed patients phase, and soothing music in dining hall phase. Measured BMI and caloric intake among patients. (Wong 2008)
Large simple trial				(none found)
Multi-level nested trial	A research design in which levels of one factor are hierarchically subsumed under (or nested within) levels of another factor.			(none found)
Pilot study	Small-scale tests of methods and procedures to be used on a larger scale if the pilot study demonstrates that these methods and procedures can work.	Determine whether an intervention or study is feasible on a small-scale prior to full investment in study	No full study completed Can not be used for evaluating outcomes/therapy/behavior	Telehealth: Feasibility of connecting dementia patients experiencing aphasia (N=34) to a speech-language pathologist via telepractice (Rogalski 2016)

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Pragmatic trial	Randomized controlled trial designed to determine the risks, benefits, and costs of an intervention as it would occur in routine clinical practice. This is achieved by including a broader range of patients, study sites, and outcomes to address needs of patients, clinicians, and other stakeholders. (Pragmatic Clinical Trial)	Generalizable to usual care/ clinical settings/practice		Cognitive stimulation therapy: Single-blind RCT conducted in nine care homes and nine community services in UK White dementia patients. All participants received 7 weeks of CST training, then randomized to receive 24-week maintenance CST therapy or treatment as usual. (Orrell 2014)
Pre-post study	A method for assessing the impact of an intervention by comparing scores on a variable before and after an intervention occurs.	Measure individual change over time	Impact of attention Repeat measurement	Staff training: Staff training to adapt ADL activities to Piaget cognitive developmental stages for patients with Alzheimer's and related disorders in a VA nursing home (N=63) versus control patients in a community nursing home (N=30). Pre/post test on the Nursing home Behavior Problem Scale (Matteson 1997)
Quasi-experimental	A study where participants are assigned to a treatment, procedure, or intervention by methods that are not random.	see Non-randomized		
Stepped-wedge trial	A randomized trial design that involves sequential roll-out of an intervention to participants (individuals or clusters) over a number of time periods.	Pragmatic study design of clusters Useful for service delivery interventions Useful for studies that do not rely on individual patient recruitment Useful in cases where substantial cluster-level effects are present Source: Hemming 2015	Sample size calculations and analyses must be robust to clustering and confounding effect of time Potential for selection bias in studies with individual patient recruiting Source: Hemming 2015	Nurse-led monitoring: five care homes in the UK (N=43 service users) randomized to 5 sequential monthly intervals evaluating an intervention of nurse monitoring to alleviate under-reporting of adverse effects of prescribed medicines, facilitate shared decision-making with service users and identify problems that merit attention.