

Clinical Trials and Alzheimer's Disease

On this resource list:

Alzheimer's Association Publications

General

Perspectives on Informed Consent

General

Persons with Dementia

Surrogate Decision Makers

Prevention Trials

Research and Design Methods

Resources for Families

Resources for Professionals

Alzheimer's Association Publications

Clinical studies.

Chicago, IL: Alzheimer's Association National Office, 2007.

Covers information on participating in a clinical trial, how clinical trials work, accuracy and safety of trials, informed consent, matching participants to studies, and how to find a study.

http://www.alz.org/alzheimers_disease_clinical_studies.asp

Clinical trials index.

Chicago, IL: Alzheimer's Association National Office, 2007.

http://www.alz.org/alzheimers_disease_clinical_trials_index.asp

Ethical issues in dementia research (with special emphasis on informed consent).

Chicago, IL: Alzheimer's Association National Office, 1997.

http://www.alz.org/national/documents/statements_ethicalissues.pdf

General

Articles, Journal

Caban-Holt, A.; Bottiggi, K.; Schmitt, F.A. Measuring treatment response in Alzheimer disease clinical trials. *Geriatrics*. Jun 2005; vol. Suppl, pp. 3-8.

Green-Field Library does not own.

Ferris, S.H. Clinical trials in AD: are current formats and outcome measures adequate. *Alzheimer Disease and Associated Disorders*. 2002; vol. 16(Suppl 1), pp. S13-S17.

Green-Field Library owns.

Jeste, D.V.; Palmer, B.W.; Appelbaun, P.S.; et al. A new brief instrument for assessing decisional capacity for clinical research. *Archives of General Psychiatry*. Aug 2007; vol. 64(8), pp. 966-974.

Green-Field Library does not own.

Karlawish, J.H.; Clark, C.M. Addressing the challenges of transforming laboratory advances into Alzheimer's disease treatments. *Neurobiology of Aging*. Nov-Dec 2002; vol. 23(6), pp. 1043-1049.

Green-Field Library owns.

Lidz, C.W.; Appelbaum, P.S.; Grisso, T.; et al. Therapeutic misconception and the appreciation of risks in clinical trials. *Social Science and Medicine*. May 2004; vol. 58(9), pp. 1689-1697.

Green-Field Library does not own.

Mani, R.B. The evaluation of disease modifying therapies in Alzheimer's disease: a regulatory viewpoint. *Statistics in Medicine*. Jan 30, 2004; vol. 23(2), pp. 305-314.

Green-Field Library does not own.

Mohs, R.C. The clinical syndrome of Alzheimer's disease: aspects particularly relevant to clinical trials. *Genes, Brain, and Behavior*. Apr 2005; vol. 4(3), pp. 129-133.

Green-Field Library does not own.

Scheltens, P. Barkhof, F. Structural neuroimaging outcomes in clinical dementia trials, with special reference to disease modifying designs. *Journal of Nutrition, Health, and Aging*. Mar-Apr 2006; vol. 10(2), pp. 123-128.

Green-Field Library does not own.

Sevick, M.A.; McConnell, T.; Meuender, M. Conducting research related to treatment of Alzheimer's disease. Ethical issues. *Journal of Gerontological Nursing*. Feb 2003; vol. 29(2), pp. 6-12.

Green-Field Library owns.

Vellas, B.; Andrieu, S.; Sampaio, C. et al. Disease-modifying trials in Alzheimer's disease: a European task force consensus. *Lancet Neurology*. Jan 2007; vol. 6(1), pp. 56-62.
Green-Field Library owns.

Perspectives on Informed Consent - General

Articles, Journal

Beattie, B.L. Consent in Alzheimer's disease research: risk/benefit factors. *Canadian Journal of Neurological Sciences*. Mar 2007; vol. 34(Suppl 1), pp. S27-S31.
Green-Field Library does not own.

Cahill, M.; Wichman, A. Research involving persons with cognitive impairments: results of a survey of Alzheimer disease research centers in the United States. *Alzheimer's Disease and Associated Disorders*. Jan-Mar 2000; vol. 14(1), pp. 20-27.
Green-Field Library owns.

Fisk, J.D. Ethical considerations for the conduct of antidementia trials in Canada. *Canadian Journal of Neurological Sciences*. Mar 2007; vol. 34(Suppl 1), pp. S32-S36.
Green-Field Library does not own.

Karlawish, J.H.; Knopman, D.; Clark, C.M.; et al. Informed consent for Alzheimer's disease clinical trials: a survey of clinical investigators. *IRB*. Sep-Oct 2002; vol. 24(5), pp. 1-5.
Green-Field Library does not own.

Michels, R. Research on persons with impaired decision making and the public trust. *American Journal of Psychiatry*. May 2004; vol. 161(5), pp. 777-779.
Green-Field Library does not own.

Stocking, C.B.; Hougham, G.W.; Baron, A.R.; et al. Are the rules for research with subjects with dementia changing?: views from the field. *Neurology*. Dec 23, 2003; vol. 61(12), pp. 1649-1651.
Green-Field Library owns.

Perspectives on Informed Consent - Persons with Dementia

Articles, Journal

Buckles, V.D.; Powlishta, K.K.; Palmer, J.L.; et al. Understanding of informed consent by demented individuals. *Neurology*. Dec 23, 2003; vol. 61(12), pp. 1662-1666.
Green-Field Library owns.

Karlwish, J.H.; Casarett, D.J.; James, B.D. Alzheimer disease patients' and caregivers' capacity, competency, and reasons to enroll in early-phase Alzheimer's disease clinical trials. *Journal of the American Geriatric Society*. Dec 2002; vol. 50(12), pp. 2019-2024.
Green-Field Library owns.

Kim, S.Y.; Kim, H.M.; McCallum, C.; et al. What do people at risk for Alzheimer disease think about surrogate consent for research? *Neurology*. Nov 8, 2005; vol. 65(9), pp. 1395-1401.
Green-Field Library owns.

Book

Wilkinson, H. (ed.) *The perspectives of people with dementia: research methods and motivations*. Philadelphia, PA: Jessica Kingsley Publishers, 2002. ISBN: 1843100010.
Green-Field Library Call No.: WM 220 P467 2002

Perspectives on Informed Consent - Surrogate Decision Makers

Articles, Journal

Beck, C.; Shue, V. Surrogate decision-making and related issues. *Alzheimer's Disease and Associated Disorders*. Apr-Jun 2003; vol. 17(Suppl 1), pp. S12-S16.
Green-Field Library owns.

Karlwish, J.H. Living with dementia: caregiver perspectives. *LDI Issue Brief*. Jun 2002; vol. 7(8), pp. 1-4.
Green-Field Library does not own.

Kim, S.Y.; Appelbaum, P.S.; Jeste, D.V.; et al. Proxy and surrogate consent in geriatric neuropsychiatric research: update and recommendations. *American Journal of Psychiatry*. May 2004; vol. 161(5), pp. 797-806.
Green-Field Library does not own.

Lingler, J.H.; Parker, L.S.; DeKosky, S.T.; et al. Caregivers as subjects of clinical drug trials: a review of human subjects protection practices in published studies of Alzheimer's disease pharmacotherapies. *IRB*. May-Jun 2006; vol. 28(3), pp. 11-18.
Green-Field Library does not own.

Mastwyk, M.; Ritchie, C.W.; LoGiudice, D.; et al. Carer impressions of participation in Alzheimer disease clinical trials: what are their hopes? And is it worth it? *International Journal of Psychogeriatrics*. Mar 2002; vol. 14(1), pp. 39-45.
Green-Field Library owns.

Sugarman, J.; Cain, C.; Wallace, R.; et al. How proxies make decisions about research for patients with Alzheimer's disease. *Journal of the American Geriatric Society*. Aug 2001; vol. 49(8), pp. 1110 -1119. Green-Field Library owns.

Prevention Trials

Article, Journal

Ferris, S.H.; Aisen, P.S.; Cummings, J.; et al. ADCS Prevention Instrument Project: overview and initial results. *Alzheimer Disease and Associated Disorders*. Oct-Dec 2006; vol. 20(4 Suppl 3), pp. S109-S123. Prevention trials are long and require large numbers of subjects, making them costly and requiring a high burden of participation for subjects. The current study focused on developing instruments that can be completed at home and in the clinic. Green-Field Library owns.

Issues, Journal

Ferris, S. ADCS Prevention Instrument Project. *Alzheimer's Disease and Associated Disorders*. Oct-Dec 2006; vol. 20(4 Suppl 3), pp. S107-S208. A supplement to *Alzheimer's Disease and Associated Disorders* describes the ADCS (Alzheimer's Disease Cooperative Study) Prevention Instrument Project for developing new or improved instruments and assessment methods for evaluating treatment efficacy in Alzheimer disease (AD) clinical trials. Green-Field Library owns.

Vellas, B.D.; Thal, L. (eds.) Prevention trials in the field of Alzheimer's disease. *Neurology*. Nov 14, 2006; vol. 67(Suppl 3), pp. S1- S22. A supplement to *Neurology* covering prevention trials including articles on maintaining adherence and retention in dementia prevention trials, dropouts and refusals in observational studies, and more. Green-Field Library owns.

Research Methods & Design

Articles, Journal

Becker, R.E. Treating Alzheimer's disease: do clinical trial methods produce unnecessary practitioner dilemmas? *American Journal of Alzheimer's Disease and Other Dementias*. Mar-Apr 2006; vol. 21(2), pp. 81-84. Green-Field Library owns.

Dunn, L.B.; Nowrangi, M.A.; Palmer, B.W.; et al. Assessing decisional capacity for clinical research or treatment: a review of instruments. *American Journal of Psychiatry*. Aug 2006; vol. 163(8); pp. 1323-1334.
Green-Field Library does not own.

Gold, M. Study design factors and patient demographics and their effect on the decline of placebo-treated subjects in randomized clinical trials in Alzheimer's disease. *Journal of Clinical Psychiatry*. Mar 2007; vol. 68(3), pp. 430-438.
Green-Field Library does not own.

Hellstrom, I.; Nolan, M.; Nordenfelt, L.; et al. Ethical and methodological issues in interviewing persons with dementia. *Nurse Ethics*. Sep 2007; vol. 14(5), pp. 608-619.
Green-Field Library does not own.

Huntington, I.; Robinson, W. The many ways of saying yes and no: reflections on the research coordinator's role in recruiting research participants and obtaining informed consent. *IRB*. May-Jun 2007; vol. 29(3), pp. 6-10.
Green-Field Library does not own.

Lockwood, P.; Ewy, W.; Hermann, D.; et al. Application of clinical trial simulation to compare proof-of-concept study designs for drugs with a slow onset of effect; an example in Alzheimer's disease. *Pharmaceutical Research*. Sep 2006; vol. 23(9), pp. 2050-2059.
Green-Field Library does not own.

MacKnight, C. Study design in dementia drug trials. *Canadian Journal of Neurological Sciences*. Mar 2007; vol. 34(Suppl 1), pp. S19-S22.
Green-Field Library does not own.

Martin, B.K.; Breitner, J.C.; Evans, D.; et al. The trialist, meta-analyst, and journal editor: lessons from ADAPT. *American Journal of Medicine*. Mar 2007; vol. 120(3), pp. 192-193.
Green-Field Library does not own.

Reiman, E.M. Clinical trials and tribulations. *Journal of Clinical Psychiatry*. Mar 2007; vol. 68(3), pp. 428-429.
This article specifically addresses Alzheimer's disease.
Green-Field Library does not own.

Shadlen, M.F.; McCormick, W.C.; Larson, E.B. Research agenda for understanding Alzheimer disease in diverse populations: work group on cultural diversity, Alzheimer's Association. *Alzheimer's Disease and Associated Disorders*. 2002; vol. 16(Suppl 2), pp. S96-S100.
Green-Field Library owns.

Stocking, C.B.; Hougham, G.W.; Baron, A.R.; et al. Ethics reporting in publications about research with Alzheimer's disease patients. *Journal of the American Geriatric Society*. Feb 2004; vol. 52(2), pp. 305-310.
Green-Field Library owns.

Thal, L.J.; Kantarci, K.; Reiman, E.M. The role of biomarkers in clinical trials for Alzheimer disease. *Alzheimer's Disease and Associated Disorders*. Jan-Mar 2006; vol. 20(10), pp. 6-15.
Green-Field Library owns.

Wilcok, G. Outcomes for disease modifying trials. *Journal of Nutrition, Health, and Aging*. Jul-Aug 2007; vol. 11(4), pp. 318-319.
Green-Field Library does not own.

Xiong, C.; Yu, K.; Gao, F.; et al. Power and sample size for clinical trials when efficacy is required in multiple endpoints: application to an Alzheimer's treatment trial. *Clinical Trials*. 2005; vol. 2(5), pp. 387-393.
Green-Field Library does not own.

Book

Schneider, L. Rating scales and outcomes used in clinical trials. IN: Richter, R.W.; Zoeller Richter, B. *Alzheimer's disease: a physicians guide to practical management*, pp. 337-348.
Humana Press, 2004. ISBN: 0896038912
<http://books.google.com/books?id=UFIMUdZiRC8C&pg=PA337&lpg=PA337&dq=Dementia+Rating+Scales+Overview+alzheimer-insights&source=web&ots=U5Nf1IT6vu&sig=8WJ-9egjYrTzA-aGhFx3OQsaYqc#PPA337.M1>
Green-Field Library Call No.: WM 220 A47565 2004

Resources for Families

For additional resources on clinical trials, see Alzheimer's Association Publications.

Web Resources

Alzheimer's disease fact sheet.
Bethesda, MD: ADEAR (Alzheimer Disease Education & Referral Center), 2006.
Includes information on new areas of research and clinical trials.
<http://www.nia.nih.gov/node/4446>

Alzheimer's disease. Clinical trials. A guide for patients.
New York, NY: WebMD. 2007.
<http://www.webmd.com/alzheimers/guide/alzheimers-patient-guide>

CenterWatch: clinical trials listing service.

Boston, MA: CenterWatch.com

A resource for patients interested in participating in clinical trials with background information about the process, a database of completed studies, industry news, educational forums, and more.

<http://www.CenterWatch.com>

CISCRP (Center for Information and Study on Clinical Research Participation)

A nonprofit agency with the mission to educate, inform, and promote greater awareness of the clinical trial process.

Dedham, MA: Center for Information and Study on Clinical Research Participation.

<http://www.ciscrp.org>

Clinical trials.

Bethesda, MD: ADEAR (Alzheimer's Disease Education & Referral Center), 2007.

The Alzheimer's Disease Clinical Trials Database is a joint project of the U.S. Food and Drug Administration (FDA) and the National Institute on Aging (NIA) maintained by the NIA's Alzheimer's Disease Education and Referral (ADEAR) Center.

<http://www.nia.nih.gov/Alzheimers/ResearchInformation/ClinicalTrials>

ClinicalTrials.gov.

Bethesda, MD: National Institutes of Health.

"ClinicalTrials.gov is a registry of federally and privately supported clinical trials conducted in the United States and around the world. ClinicalTrials.gov gives you information about a trial's purpose, who may participate, locations, and phone numbers for more details. This information should be used in conjunction with advice from health care professionals." The home page is at <http://clinicaltrials.gov>. Trials on Alzheimer's disease are at

<http://clinicaltrials.gov/ct/screen/BrowseAny?path=%2Fbrowse%2Fby-condition%2Faz%2FA%2FD000544%2BAlzheimer%2BDisease&recruiting=true>

ClinicalTrialsFeeds.org and Subscribing to ClinicalTrialsFeed.org.

Bethesda, MD: U.S. National Institutes of Health.

Links families to clinical research in dementia using RSS, which updates information on clinical trials frequently. To find clinical trials in dementia and subscribe to the feed and have it downloaded to your computer visit: <http://clinicaltrialsfeeds.org/clinical-trials/results/?term=dementia>.

Clinical trials: MedlinePlus.

Bethesda, MD: National Library of Medicine, 2008.

This site is provided jointly by the U.S. National Library of Medicine and the National Institutes of Health (NIH). It features informational tutorials about a variety of topics. Content includes an interactive multimedia presentation and a printable instructional tutorial.

<http://www.nlm.nih.gov/medlineplus/clinicaltrials.html>

Clinical trials of medical treatments: why volunteer.

Washington, DC: U.S. Food and Drug Administration, 2006

<http://www.fda.gov/opacom/lowlit/cltr.html>

Drugs in clinical trials.

Waltham, MA: Alzheimer Research Forum.

<http://www.alzforum.org/dis/tre/drc/default.asp>

Frequently asked questions about clinical trials research.

Bethesda, MD: U.S. National Institutes of Health, 2007.

<http://clinicaltrialsfeeds.org/clinical-trials/info/understand>

Glossary of terms used in clinical trials.

Bethesda, MD: U.S. National Institutes of Health, 2007.

<http://clinicaltrialsfeeds.org/clinical-trials/info/glossary>

The FDA's drug review process: ensuring drugs are safe and effective.

Washington, DC: U.S. Food and Drug Administration.

<http://www.fda.gov/fdac/special/testtubetopatient/drugreview.html>

Resources for Professionals

For web resources useful to health care professionals, see also Resources for Families.

Books

Curry, L.; Shield, R.; Wetle, T. (eds.). *Improving aging and public health research.*

Washington, DC: American Public Health Association, Gerontological Society of America, 2006. ISBN: 0875530516.

Green-Field Library Call No.: WA 20.5 I34 2006

Day, S. *Dictionary for clinical trials.*

Hoboken, NJ: John Wiley & Sons, 2007. ISBN: 047005817X.

Green-Field Library Call No.: QV 13 D275d 2007

Fortwengel G. *Guide for clinical trial staff: implementing good clinical practice.*

New York, NY: Karger, 2007. ISBN: 3805576552.

Green-Field Library Call No.: W 20.5 F745 2007

Machin, D.; Day, S.; Green, S. *Textbook of clinical trials*.
Hoboken, NJ: John Wiley & Sons, 2006. ISBN: 0470010142.
Green-Field Library Call No.: WV 771 T344 2006

Multidisciplinary guidebook for clinical geriatric research.
Washington, DC: Gerontological Society of America, 2006. ISBN:
0929596099.
Green-Field Library Call No.: WT 20 M961 2006

O'Brien, J.T.; Ballard, C.; Winblad, B. (eds.). *Controlled clinical trials reports. Alzheimer's disease*.
London, UK: Science Press, 2001. ISBN: 185733723.
Green-Field Library Call No.: WM 220 A478555.

Clinical Trials in Alzheimer's Disease

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