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Underrepresentation of Working-Age and Older Adults with Disabilities in Behavioral Clinical Trials in the US: A Review of Registered Behavioral Clinical Trials

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Underrepresentation of Working-Age and Older Adults with Disabilities in Behavioral Clinical Trials in the US:

A Review of Registered Behavioral Clinical Trials

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ABSTRACT

Although working-age and older adults with disabilities are among the greatest beneficiaries of healthcare services, they are often excluded from clinical research that informs healthcare policy. The exclusion of people with disabilities from research may impact access to and quality of care for millions of Americans. We conducted a scoping review to examine the exclusion of working-age and older adults with disabilities from behavioral clinical trials. We aimed to explore whether exclusion criteria regarding diagnoses or health conditions associated with disability were strongly justified, poorly justified, or unjustified, as well as the distribution of the excluded health conditions by justification category. We conducted a systematic search of ClinicalTrials.gov on November 18, 2018, and an updated search on April 27, 2021. We searched for interventional behavioral studies that were conducted in the US, focused on working-age adults (18-64) and/or older adults (65+), and were completed from 2008-2020. We found 327 clinical trials that matched our criteria. Of 327 studies, 256 excluded at least one diagnosis or health condition. A total of 1342 exclusion criteria related to diagnoses or health conditions were listed, 76.3% of which were unjustified. Our findings provide strong evidence that people with disabilities are excluded from behavioral clinical trials, often with no or poor justification. Results support the need to develop strategies, such as including disability as a demographic variable, to minimize the exclusion of people with disabilities when the population is part of a group to which study results are generalized. When exclusion of health conditions is necessary, a clear justification should be provided.

INTRODUCTION

People with disabilities are one of the largest minority groups in the US.^{1,2} According to the Centers for Disease Control and Prevention (CDC), one in four non-institutionalized adults in the US (an estimated 61.4 million people) has a disability that impacts major life activities.³ Advances in medicine and public health are contributing to improvements in health and longevity, including for individuals with disabilities. In fact, the US population aged 65 years and older is projected to double by 2050, including a shift of people with disabilities into an aging society.⁴ In 2016, 51% of individuals with disabilities were adults between the ages of 18 and 64 (referred to in this study as "working-age"), and 41% were older adults (65 years and older). In addition, the percentage of people with disabilities related to hearing, vision, cognition, ambulation, self-care, and independent living increases greatly with age.⁵

Working-age and older adults with disabilities have a higher incidence of chronic conditions and health-related disparities than their counterparts without disabilities, and they are at greater risk of developing secondary conditions that require healthcare services, especially if they experience obesity, physical inactivity, or smoke.^{2,6,7} While working-age and older adults with disabilities are among the greatest potential beneficiaries of healthcare services, they are often not represented in clinical trials.^{8,9} Clinical trials are the universally accepted gold standard of evidence-based clinical practice. Well-conducted, randomized, double-blind clinical studies are used as the basis for both clinical and policy decisions on healthcare priorities.¹⁰ Failure to provide representation of individuals with disabilities in health research considerably impairs the external validity of studies, limiting the application of research findings and subsequent healthcare for more than 61 million working-age and older adults with disabilities in the US.³

International ethical guidelines for health research involving humans, such as those published by the Council for International Organizations of Medical Sciences in collaboration with the World Health Organization, state that participants in clinical trials should be selected to ensure equitable distribution of the burdens and benefits of the research, and exclusion criteria must be scientifically and ethically justified rather than arbitrarily or conveniently chosen.¹¹ However, it is known that researchers do not always accomplish this aim.^{12,13} A recent review of randomized controlled trials and clinical trials published between 2007 and 2011 in the six highest-impact medical journals revealed that only 2% of clinical trials included people with intellectual disabilities when at least 70% of these trials could have included them with only minor accommodations and without compromising research integrity.¹⁴

While it is acceptable to use clear justifications to exclude individuals for biological reasons (e.g., sex), researchers should never exclude populations for being vulnerable, requiring accommodations, or taking more time to complete study procedures.¹⁵ Excluding people without a strong justification is unethical based on principles of equity and justice and defies the National Institutes of Health (NIH) Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research, which state that "women and members of minority groups and their subpopulations must be included in all NIH-funded clinical research, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research."16 Because research findings are used to inform healthcare, the exclusion of people with disabilities from research may impact overall access to and quality of care for millions of people in the US. People with disabilities experience limited access to healthcare and research facilities, and they often feel that they are not listened to and that their needs and requests for accommodations are not understood.¹⁷ If a specific treatment is potentially useful to a specific population, that population should be included in the study.

Empirical evidence on the systematic exclusion of working-age and older adults with disabilities in health research is lacking.^{13,18} Quantifying this problem is an important step to addressing the integration of people with disabilities, who are often marginalized. Therefore, the purpose of this review was to explore the extent to which people with disabilities are excluded from behavioral clinical trials. Specifically, we aimed to examine the level of exclusion of people with diagnoses or health conditions associated with disability and to examine the justification for such exclusion criteria.

METHODS

The scoping review approach of Arksey and O'Malley¹⁹ was used as a guide for this study.

Identifying the Research Question

The focus of our scoping review was to explore the exclusion of working-age and older adults with disabilities from behavioral clinical trials that provide evidence for the fields of rehabilitation, public health, and behavioral medicine. We aimed to identify the breadth of studies excluding people with diagnoses or health conditions using the following initial research questions: (1) how well are exclusion criteria for diagnoses or health conditions justified; (2) what are the characteristics (e.g., participants' mean age and gender percentages, number of participants enrolled, timeframe of the trial) of studies that provided different levels of justification for excluding people with diagnoses or health conditions, and how do those characteristics compare across studies with different levels of justification; and (3) which diagnoses or health conditions are most frequently excluded, and to what extent is each excluded diagnosis or health condition justified?

Identifying Relevant Studies

We conducted a systematic search on ClinicalTrials.gov, a database of privately and publicly funded clinical studies conducted around the world. The first search was conducted on November 18, 2018, and was repeated on April 27, 2021. In the updated search, we applied the following filters to reflect our inclusion criteria: "completed studies," "studies with results," "interventional studies," "United States," "adult (18–64)," "older adult (65+)," "studies that accept healthy volunteers," and "primary completion date [the date on which the last participant was examined or received an intervention to collect final data or on which all the data for the primary outcome measure were collected] from 01/01/2008 to 12/31/2020." Because the search targeted behavioral interventions, we applied "behavioral" in the intervention/treatment field on the advanced search page. This excluded studies that focused on other interventions, such as "biological," "device," "drug," "dietary supplement," "combination product," "diagnostic test," "genetic," "procedure," "radiation," and "other."

A spreadsheet of these results that contained data regarding the characteristics and eligibility criteria for each study was exported from ClinicalTrials.gov. The spreadsheet included the following fields: study title, intervention, outcome measures, sex, age, enrollment, funders, study start date, study completion date, and eligibility criteria (inclusion and exclusion criteria). Studies were further excluded if participants were health providers or if the age variable included "child" even after application of the age filter.

Study Selection

As of the updated search on April 27, 2021, our search strategy retrieved 4571 studies. After the exclusion of clinical trials that focused on or included non-behavioral interventions, we were left with a total of 421 behavioral clinical trials. Fourteen clinical trials were excluded because they focused on health providers, and 80 were excluded because they included children, leaving 327 clinical trials that qualified for the review (Figure 1).

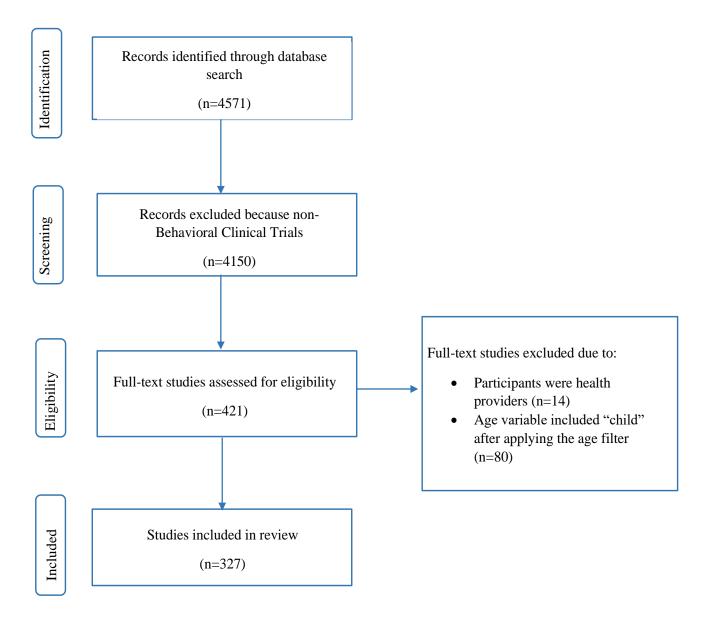


Figure 1. Flow of identified behavioral clinical trials

Data Extraction

We added columns to create our own variables and classifications to the exported spreadsheet from ClinicalTrials.gov that contained the final studies for the review. For this study, we considered "disability" based on the Americans with Disabilities Act (ADA), which defines a person with a disability as "a person who has a physical or mental impairment that substantially limits one or more major life activities. This includes people

who have a record of such an impairment, even if they do not currently have a disability."³² We reviewed each trial's exclusion and inclusion criteria and the characteristics of each study. If a study had publications listed on ClinicalTrials.gov, we also reviewed the articles to ensure that the inclusion and exclusion criteria were captured in the spreadsheet. Inclusion criteria were examined because they could imply exclusion of certain conditions. For example, requiring "sufficient cognitive skills to provide informed consent and actively participate" for a study implies that people with a cognitive impairment were excluded.

Evaluation and Classification of Each Clinical Trial

A classification system was developed to categorize eligibility criteria that might negatively impact the inclusion of working-age and older adults with disabilities in clinical trials. Each exclusion (or sometimes inclusion) criterion was classified as "strongly justified," "poorly justified," or "unjustified" based on the NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research.^{15,16} "Strongly justified" exclusion criteria provided a specific rationale for the exclusion of the diagnosis or health condition such as inappropriateness of the study with respect to the health of the potential participant or inappropriateness with respect to the purpose of the research. "Poorly justified" criteria excluded potential participants for unclear reasons not explicitly linked to the condition.²⁰ Studies with "unjustified" exclusion of diagnoses or health conditions did not provide their rationale for exclusion. If ClinicalTrials.gov did not provide sufficient information for criteria classification, we also searched for the publications online to find the information. Eligibility criteria that were irrelevant to diagnoses or health conditions (e.g., English speaking, living in a certain location) were not classified.

If studies excluded a diagnosis or health condition twice with differing levels of justification, both were recorded. For example, one study excluded "uncontrolled serious mental illness...in the past 6 months" without justification and also excluded individuals with "mental conditions that would prohibit the participant from completing the protocol." This study was listed under two justification categories (i.e., unjustified and poorly justified, respectively) to reflect the number of exclusion criteria specifically identifying mental health.

The above classification process was conducted by three reviewers independently. Each record was classified by two reviewers. Any discrepancies in criteria classification between reviewers were discussed until a consensus was reached.

Data Synthesis

Descriptive data were presented as counts and percentages for categorical variables. All data were analyzed using SPSS Version 27 (IBM, 2020) and Microsoft Excel 2013.

RESULTS

Characteristics of the Studies

Characteristics of the 327 clinical trials included in the review are described in Table 1. Most studies included both male and female participants (78%) and both working-age and older adults (18–65+ years; 69.7%). The majority of clinical trials (45.6%) enrolled 6–100 participants. Most studies were funded by "US Federal Agencies/Other" (44.3%), and 38.2% were funded by "Other," such as individuals, universities, and community-based organizations. Approximately 28% of studies had a duration of 37–60 months from the study start date (i.e., the estimated date that the clinical trial opened for recruitment of participants or the actual date when the first participant was enrolled) to the study completion date.

		n (%)
Gender	Only Female	50 (15.3)
	Only Male	22 (6.7)
	Multiple genders	255 (78.0)
Age	Working-age adults (18–64)	79 (24.2)
	Older adults (65+)	20 (6.1)
	Adults and older adults (18–65+)	228 (69.7)
Number of enrolled	6–100	149 (45.6)
participants	101–250	78 (23.9)
	251–500	53 (16.2)
	501+	47 (14.4)

Table 1. Summary of Characteristics of the Clinical Trials (n=327)

Funder type	US Federal Agencies	44 (13.5)
	US Federal Agencies/Other	145 (44.3)
	US Federal Agencies/Industry	1 (0.3)
	US Federal Agencies/Industry/Other	3 (0.9)
	Industry	2 (0.6)
	Industry/Other	7 (2.1)
	Other	125 (38.2)
Start year	1998–2007	42 (12.8)
	2008–2017	255 (78.0)
	2018–2020 (updated search)	30 (9.2)
Study duration (months)	<4	9 (2.8)
	04–12	64 (19.6)
	13–24	69 (21.1)
	25–36	58 (17.7)
	37–60	93 (28.4)
	61+	34 (10.4)

Justification for Exclusion Criteria

Of 327 studies, 256 excluded at least one diagnosis or health condition; the other 71 studies had no exclusion criteria related to diagnoses or health conditions. The 256 studies had 1342 total exclusions related to diagnoses or health conditions, as each study could have multiple exclusion criteria. Among these 1342 criteria, 76.3% were unjustified (i.e., no reason for exclusion provided), 2.1% were poorly justified, and 21.7% were strongly justified. Of the strongly justified exclusion criteria, 13.8% were justified as inappropriate with respect to the purpose of the research, 6.0% were justified as inappropriate with respect to both the research purpose and potential participants' health (Table 2).

Diagnoses and Health Conditions Excluded

Among all health conditions, mental health conditions (including related treatment) were most often listed as exclusion criteria (total 373 times), the majority of which were unjustified (n=316). This trend was true for all health conditions: the majority of exclusions were made without justification.

Among the exclusion criteria that were strongly justified due to the health of potential participants, the most common conditions were unspecified medical conditions (27.5%) and cardiovascular conditions (25%). The primary reason for exclusion was contraindication with participation in the intervention (e.g., medical or other contraindications to weight loss, study procedures that may make participation unsafe and/or uncomfortable). Among criteria that were strongly justified as unsuitable for the research purpose, mental health condition (20%) was the most common (See Table 2). The most common reason given was that the condition could interfere with the intervention or was likely to confound the results.

Table 2. Percentages of Health Conditions by Justification Category (n=1342), n (%)

Exclusion Criteria

Strongly Justified

Unjustified

	Health of participants (n=80, 6.0%)	Purpose of research (n=185, 13.8%)	Health of participants & purpose of research (n=25, 1.9%)	Poorly Justified (n=28, 2.1%)	(n=1024, 76.3%)	Total number in each condition (n=1342)
Mental Health Condition (including Tx)	7 (8.8)	37 (20.0)	8 (32.0)	5 (17.9)	316 (30.9)	373
Physical Impairment	6 (7.5)	19 (10.3)	2 (8.0)	2 (7.1)	44 (4.3)	73
Cardiovascular Condition	20 (25.0)	12 (6.5)	3 (12.0)	0 (0.0)	110 (10.7)	145
Endocrine/Metabolic Condition	1 (1.3)	0 (0.0)	3 (12.0)	0 (0.0)	46 (4.5)	50
Respiratory System Condition	2 (2.5)	5 (2.7)	0 (0.0)	0 (0.0)	31 (3.0)	38
Neurological Condition	5 (6.3)	25 (13.5)	0 (0.0)	9 (32.1)	120 (11.7)	159
Autoimmune Condition	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	7 (0.7)	8
Renal Condition	2 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	13 (1.3)	15
Gastrointestinal Condition (e.g., inflammatory bowel disease, colitis, peptic ulcer, polyps)	1 (1.3)	3 (1.6)	0 (0.0)	0 (0.0)	11 (1.1)	15
Liver Condition	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	13 (1.3)	13
Hematologic Condition	2 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.8)	10
HIV	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	15 (1.5)	17
Cancer	2 (2.5)	1 (0.5)	0 (0.0)	0 (0.0)	27 (2.6)	30
Functional Impairment—ADL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.8)	8
Visual Impairment	0 (0.0)	5 (2.7)	0 (0.0)	3 (10.7)	14 (1.4)	22
Hearing Impairment	0 (0.0)	3 (1.6)	0 (0.0)	2 (7.1)	18 (1.8)	23
Pain	2 (2.5)	3 (1.6)	0 (0.0)	0 (0.0)	1 (0.1)	6
Speech/Language Disorder (voice impairment, aphasia, or unspecified)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	6 (0.6)	7
Unspecified Comorbidities	1 (1.3)	3 (1.6)	0 (0.0)	1 (3.6)	3 (0.3)	8
Unspecified Medical Condition	22 (27.5)	35 (18.9)	7 (28.0)	4 (14.3)	93 (9.1)	161
Under Treatment—Other Than Mental Health–related Tx	5 (6.3)	22 (11.9)	2 (8.0)	1 (3.6)	90 (8.8)	120
Other Conditions*	2 (2.5)	8 (4.3)	0 (0.0)	1 (3.6)	30 (2.9)	41

Note. A detailed table with all subcategories can be found in the Appendix. Tx=treatment, ADL=activity of daily living.

^{*}Conditions with two cases or fewer, including restless leg syndrome, disability claim, systemic condition, organ transplantation, balance disorder, vestibular disorder, dizziness, apnea, multi-chronic infections, immunosuppressive condition, dietary condition, obesity, chewing/swallowing impairment, unspecified communication condition, unspecified sensory condition, fibromyalgia, and osteoporosis.

DISCUSSION

Of 327 behavioral clinical trials included in this scoping review, 256 studies listed 1342 exclusion criteria related to diagnoses or health conditions, with some studies excluding multiple conditions. Among the 1342 criteria, most (76.3%) were unjustified. Eligibility

criteria in clinical trials should help identify a population of interest for which an intervention has the greatest probability to produce a significant effect. While Consolidated Standards of Reporting Trials (CONSORT) guidelines and the Uniform Requirements for Manuscripts Submitted to Biomedical Journals have been major steps forward in improving the transparency of clinical trials,^{21,22} this review found a high percentage of unjustified exclusion criteria. In some cases, the reason for exclusion may seem obvious to clinical researchers (e.g., contraindications), but it cannot be assumed that all readers have the background knowledge to understand why a certain condition was excluded. Therefore, when exclusions of diagnoses or health conditions are necessary, we recommend clearly explaining the rationale for each criterion in the Methods section and avoiding non-specific terms like "medical illness," "health problems," "chronic condition," or "significant disease." The clarification will allow researchers to better follow the NIH Policy and Gudelines on The Inclusion of Women and Minorities as Subjects in Clinical Research, which require a clear and compelling justification for excluding certain minority groups due to inappropriateness with respect to the health of the subjects or the purpose of the research.¹⁶

The unprecedented shift in the number of people living longer will demand changes to healthcare, housing, policy, community development, and long-term supports and services^{4,23} so that people can age successfully in their homes and communities.²⁴ Service networks are experiencing new challenges, as they customarily address disability or aging needs but not a combination of the two. This places new demands on long-term supportive service providers and highlights critical gaps in services to support aging in place and community participation for individuals with disabilities.²⁵⁻³⁰ However, there is still limited evidence to inform clinical practice, community-based programming, and public policy to support positive aging outcomes for people with disabilities.³¹ Exclusion of diagnoses or health conditions in studies of older adults is of particular concern for external validity, as chronic conditions are prevalent in older adults. Older adults and people with disabilities are also high users of the healthcare system, so their exclusion from health research limits the applicability of findings for a significant number of people. In light of the shifting demographic and healthcare landscape, additional information about the conditions of adults and older adults with disabilities is needed so that healthcare professionals can address the needs of this growing population.

The results of our scoping review support the need to develop strategies to minimize exclusion of working-age and older adults with disabilities from research when the population is part of a group to which the results are generalized. Thus, one crucial strategy is to make careful, calculated decisions in the study design phase.³² This includes considering potential benefits for people with disabilities and whether the treatment effect would be overshadowed by physiological changes due to the condition. As such, researchers must include disability as a demographic variable, such as age, sex, race, or

ethnicity, to precisely translate research findings and improve health outcomes for this population.¹⁸

LIMITATIONS

While this study provides strong evidence that working-age and older adults with disabilities are excluded from clinical trials of behavioral interventions, this study had limitations that must be discussed. Our review focused on clinical trials of behavioral interventions. Therefore, our findings may only be applicable to this particular clinical domain. In addition, we conducted our search using the ClinicalTrials.gov database; some early studies may not be registered on ClinicalTrials.gov. For this reason, a future replication of this scoping review using additional databases such as PUBMED, EMBASE, CINAHL, and WOS may be considered. Finally, our scoping review included only studies that were conducted in the US. Future reviews may examine the exclusion of diagnoses and health conditions in other regions using other databases.

CONCLUSIONS

Although ethical guidelines require justification for exclusion of people with disabilities in research, this scoping review has revealed that justification is often not provided in clinical trials of behavioral interventions. It is crucial to be precise when defining eligibility criteria and to provide strong justification for each exclusion criterion to maintain high internal and external validity by accurately representing all populations who can benefit from the results.³²

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Declaration of Interests

The authors declare no potential conflicts of interest with respect to the research, authorship, or publication of this report.

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REFERENCES

- 1. Brucker DL, Houtenville AJ. People with disabilities in the United States. *Archives of Physical Medicine and Rehabilitation*. 2015;96(5):771-774.
- 2. Iezzoni LI. Eliminating health and health care disparities among the growing population of people with disabilities. *Health Affairs*. 2011;30(10):1947-1954.
- 3. Okoro CA, Hollis ND, Cyrus AC, Griffin-Blake S. Prevalence of disabilities and health care access by disability status and type among adults—United States, 2016. *Morbidity and Mortality Weekly Report*. 2018;67(32):882.
- 4. Ortman JM, Velkoff VA, Hogan H. *An Aging Nation: The Older Population in the United States.* United States Census Bureau, Economics and Statistics Administration; 2014.
- 5. 2017 Disability Statistics Annual Report. University of New Hampshire; 2018.
- 6. Kirschner KL, Breslin ML, Iezzoni LI, Sandel E. Attending to inclusion: People with disabilities and health-care reform. *PM R*. 2009;1(10):957-963.
- 7. Krahn GL, Reyes M, Fox M. Toward a conceptual model for national policy and practice considerations. *Disability and Health Journal*. 2014;7(1):13-18.
- 8. Meyers AR, Andresen EM. Enabling our instruments: Accommodation, universal design, and access to participation in research. *Archives of Physical Medicine and Rehabilitation*. 2000;81:S5-S9.
- 9. Feldman MA, Battin SM, Shaw OA, Luckasson R. Inclusion of children with disabilities in mainstream child development research. *Disability & Society*. 2013;28(7):997-1011.
- 10. Hansson SO. Why and for what are clinical trials the gold standard? *Scandinavian Journal of Public Health*. 2014;42(13_suppl):41-48.
- 11. Council for International Organizations of Medical Sciences. *International Ethical Guidelines for Health-Related Research Involving Humans*. 2017. Retrieved from: https://cioms.ch/publications/product/international-ethical-guidelines-for-health-related-researchinvolving-humans/
- 12. Schmidt AF, Groenwold RH, Van Delden JJ, et al. Justification of exclusion criteria was underreported in a review of cardiovascular trials. *Journal of Clinical Epidemiology*. 2014;67(6):635-644.
- 13. Van Spall HG, Toren A, Kiss A, Fowler RA. Eligibility criteria of randomized controlled trials published in high-impact general medical journals: A systematic sampling review. *JAMA*. 2007;297(11):1233-1240.
- 14. Feldman M, Bosett J, Collet C, Burnham-Riosa P. Where are persons with intellectual disabilities in medical research? A survey of published clinical trials. *Journal of Intellectual Disability Research*. 2014;58(9):800-809.
- 15. Spong CY, Bianchi DW. Improving public health requires inclusion of underrepresented populations in research. *JAMA*. 2018;319(4):337-338.

- 16. National Institutes of Health. *NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research*. 2001. Retrieved from: https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm
- 17. Scheer J, Kroll T, Neri MT, Beatty P. Access barriers for persons with disabilities: The consumer's perspective. *Journal of Disability Policy Studies*. 2003;13(4):221-230.
- 18. Rios D, Magasi S, Novak C, Harniss M. Conducting accessible research: Including people with disabilities in public health, epidemiological, and outcomes studies. *American Journal of Public Health.* 2016;106(12):2137-2144.
- 19. Arksey H, O'Malley L. Scoping studies: Towards a methodological framework. *International Journal of Social Research Methodology*. 2005;8(1):19-32.
- 20. McDonald KE, Kidney CA. What is right? Ethics in intellectual disabilities research. *Journal of Policy and Practice in Intellectual Disabilities*. 2012;9(1):27-39.
- 21. Moher D, Schulz KF, Altman DG; for the CONSORT Group. The CONSORT statement: Revised recommendations for improving the quality of reports of parallel group randomized trials. *BMC Medical Research Methodology*. 2001;1:2.
- 22. Uniform requirements for manuscripts submitted to biomedical journals: Writing and editing for biomedical publication. *Journal of Pharmacology and Pharmacotherapeutics*. 2010;1(1):42-58.
- 23. Robison J, Shugrue N, Fortinsky RH, Gruman C. Long-term supports and services planning for the future: Implications from a statewide survey of baby boomers and older adults. *The Gerontologist*. 2013;54(2):297-313.
- 24. Johnson Jr JH, Parnell AM. The challenges and opportunities of the American demographic shift. *Generations*. 2017;40(4):9-15.
- 25. Simonsick EM, Kasper JD, Phillips CL. Physical disability and social interaction: Factors associated with low social contact and home confinement in disabled older women (The Women's Health and Aging Study). *The Journals of Gerontology Series B: Psychological Sciences and Social Sciences*. 1998;53(4):S209-S217.
- 26. Torres-Gil F, Putnam M. The growing pains of aging: Disability, aging and baby boomers. *Healthy Aging: Challenges and Solutions.* 1999:261-283.
- 27. Verbrugge LM, Yang L-S. Aging with disability and disability with aging. *Journal of Disability Policy Studies*. 2002;12(4):253-267.
- 28. LaPlante MP. Key goals and indicators for successful aging of adults with early-onset disability. *Disability and Health Journal*. 2014;7(1):S44-S50.
- 29. Reinhard SC, Kassner E, Houser A, Mollica R. Raising expectations: A state scorecard on longterm services and supports for older adults, people with physical disabilities, and family caregivers. AARP. 2014.
- 30. Gill TM, Beavers DP, Guralnik JM, et al. The effect of intervening hospitalizations on the benefit of structured physical activity in promoting independent mobility among community-living older persons: Secondary analysis of a randomized controlled trial. *BMC Medicine*. 2017;15(1):65.
- 31. Putnam M, Molton IR, Truitt AR, Smith AE, Jensen MP. Measures of aging with disability in US secondary data sets: Results of a scoping review. *Disability and Health Journal*. 2016;9(1):5-10.

- 32. Williams AS, Moore SM. Universal design of research: Inclusion of persons with disabilities in mainstream biomedical studies. *Science Translational Medicine*. 2011;3(82):82cm12-82cm12.
- 33. Hulley SB, Newman TB, Cummings SR. Choosing the study subjects: Specification, sampling, and recruitment. *Designing Clinical Research*. 2007;3:27-36.

Appendix

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		Strongly Justified	Poorly Justified	Unjustified	
Exclusion Criteria	Inappropriate: health of participants (n=80, 6.0%)	Inappropriate: purpose of research	Inappropriate: health of participants & purpose of	(n=28, 2.1%)	(n=1024, 76.3%)
		(n=185, 13.8%)	research (n=25, 1.9%)		
Mental Health Condition	7 (86.4)	37 (20.0)	8 (32.0)	5 (17.9)	316 (30.9)
Anxiety disorder—Claustrophobia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.7)
Anxiety disorder—Other (e.g., generalized social anxiety disorder, needle or blood phobias, panic disorder)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.4)
Bipolar disorder	1 (1.3)	1 (0.5)	0 (0.0)	0 (0.0)	13 (1.3)
Depressive disorders	1 (1.3)	1 (0.5)	1 (4.0)	0 (0.0)	23 (2.2)
Eating disorder (e.g., bulimia, anorexia)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	18 (1.8)
Organic brain syndrome	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	2 (0.2)
Personality disorders (e.g., borderline, schizoid or schizotypal personality disorder, narcissistic)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	4 (0.4)
Schizophrenia spectrum or other psychotic disorder	1 (1.3)	4 (2.2)	0 (0.0)	0 (0.0)	27 (2.6)
Substance-related and addictive disorder—alcohol	0 (0.0)	2 (1.1)	1 (4.0)	0 (0.0)	40 (4.0)
Substance-related and addictive disorder — drug/substance	1 (1.3)	5 (2.7)	2 (8.0)	0 (0.0)	61 (6.0)
Substance-related and addictive	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (1.1)

disorder—other (e.g., nicotine					
dependence, compulsive gambling,					
unspecified)					
Suicidal ideation	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.6)	24(2.3)
Other mental health conditions with two cases or					
fewer (e.g., attentional					
disorder, behavioral disorder,					
decisionally challenged subjects,					
dissociative disorder, legally	2(2.5)	1 (0.5)	0 (0.0)	0 (0.0)	8 (0.8)
incompetent, obsessive-					
compulsive disorder, post-					
traumatic stress disorder,					
psychological diagnostic)					
Unspecified mental health condition	1 (1.3)	19 (10.3)	1 (4.0)	4 (14.3)	43 (4.2)
Treatment for mental health condition	0 (0.0)	2 (1.1)	2 (8.0)	0 (0.0)	31(3.0)
Physical Impairment	6 (7.4)	19 (10.3)	2 (8.0)	2 (7.1)	44 (4.3)
Walk impairment	0 (0.0)	3 (1.6)	1 (4.0)	0 (0.0)	21 (2.1)
Other (e.g., hemiparesis, hip fracture,					
bone or joint replacements, motor	6 (7.5)	16 (8.6)	1 (4.0)	2 (7.1)	23 (2.2)
fluctuations, spinal stenosis,	0 (7.5)	10 (0.0)	1 (4.0)	2 (7.1)	25 (2.2)
unspecified, etc.)					
Cardiovascular Condition	20 (25.0)	12 (6.5)	3 (12.0)	0 (0.0)	110 (10.7)
Hypertension	3 (3.8)	1 (0.5)	1 (4.0)	0 (0.0)	24 (2.3)
Stroke	1 (1.3)	1 (0.5)	0 (0.0)	0 (0.0)	10 (1.0)
Other (e.g., myocardial infarction,					
cardiac arrest, peripheral					
vascular disease, congestive	16 (20.0)	10 (5.4)	2(8.0)	0 (0.0)	76 (7.4)
heart failure, coronary artery					
disease, unspecified, etc.)					
Endocrine/Metabolic Condition	1 (1.3)	0 (0.0)	3 (12.0)	0 (0.0)	46 (4.5)
Diabetes	1 (1.3)	0 (0.0)	3 (12.0)	0 (0.0)	36 (3.5)
Thyroid dysfunction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.5)
Other (e.g., phenylketonuria,	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.5)
unspecified)					
Respiratory System Condition	2 (2.5)	5 (2.7)	0 (0.0)	0 (0.0)	31 (3.0)
Apnea	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	3 (0.3)

Asthma	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.7)
Chronic Obstructive Pulmonary	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	12 (1.2)
Disease (COPD)					
Unspecified	0 (0.0)	4 (2.2)	0 (0.0)	0 (0.0)	9 (0.9)
Neurological Condition	5 (6.3)	25 (13.5)	0 (0.0)	9 (32.1)	120 (11.7)
Dementia	0 (0.0)	2 (1.1)	0 (0.0)	1 (3.6)	23 (2.2)
Epilepsy	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.2)
Seizures	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	6 (0.6)
Structural brain abnormality	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.3)
Traumatic brain injury (TBI)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	8 (0.8)
Intellectual or learning disability (e.g., pervasive developmental disability)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	10 (1.0)
Unspecified neurological condition	2 (2.5)	5 (2.7)	0 (0.0)	1 (3.6)	22 (2.1)
Unspecified cognitive disorder	2 (2.5)	14 (7.6)	0 (0.0)	7 (25.0)	46 (4.5)
Autoimmune Condition	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	7 (0.7)
Renal Condition	2 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	13 (1.3)
Gastrointestinal Condition (e.g.,					
inflammatory bowel disease,	1 (1.3)	3 (1.6)	0 (0.0)	0 (0.0)	11 (1.1)
colitis, peptic ulcer, polyps)					
Liver Condition	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	13 (1.3)
Hepatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.4)
Unspecified	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.9)
Hematologic Condition	2 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.8)
Anemia	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.5)
Other (e.g., blood diathesis, low hemoglobin)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.3)
HIV	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	15 (1.5)
Cancer	2 (2.5)	1 (0.5)	0 (0.0)	0 (0.0)	27 (2.6)
Functional Impairment—ADL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.8)
Visual Impairment	0 (0.0)	5 (2.7)	0 (0.0)	3 (10.7)	14 (1.4)
Hearing Impairment	0 (0.0)	3 (1.6)	0 (0.0)	2 (7.1)	18 (1.8)
Pain	2 (2.5)	3 (1.6)	0 (0.0)	0 (0.0)	1 (0.1)
Speech/Language Disorder (voice					
impairment, aphasia, or unspecified)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	6 (0.6)
Unspecified Comorbidities	1 (1.3)	3 (1.6)	0 (0.0)	1 (3.6)	3 (0.3)

Unspecified Medical Condition	22 (27.5)	35 (18.9)	6 (24.0)	4 (14.3)	93(9.1)
Under Treatment—Other Than for Mental Health Related Tx	5 (6.3)	22 (11.9)	2 (8.0)	1 (3.6)	90 (8.8)
Other Conditions [*]	3 (3.8)	8 (4.3)	1 (4.0)	1 (3.6)	81 (7.9)

Note. Tx = treatment, ADL=activity of daily living.

*Conditions with two cases or fewer, including restless leg syndrome, disability claim, systemic condition, organ transplantation, balance disorder, vestibular disorder, dizziness, apnea, multi-chronic infections, immunosuppressive condition, dietary condition, obesity, chewing/swallowing impairment, unspecified communication condition, unspecified sensory condition, fibromyalgia, and osteoporosis.