Addressing vulnerability in cluster randomized trials involving people living with dementia in nursing homes

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NIA IMPACT COLLABORATORY
TRANSFORMING DEMENTIA CARE

Western UNIVERSITY · CANADA

Housekeeping

- All participants will be muted
- Enter **all questions** in the Zoom **Q&A/chat box** and send to Everyone
- Moderator will review questions and ask them at the end
- Want to continue the discussion? Associated podcast released about 2 weeks after Grand Rounds
- Visit impactcollaboratory.org
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https://www.linkedin.com/company/65346172

Research team

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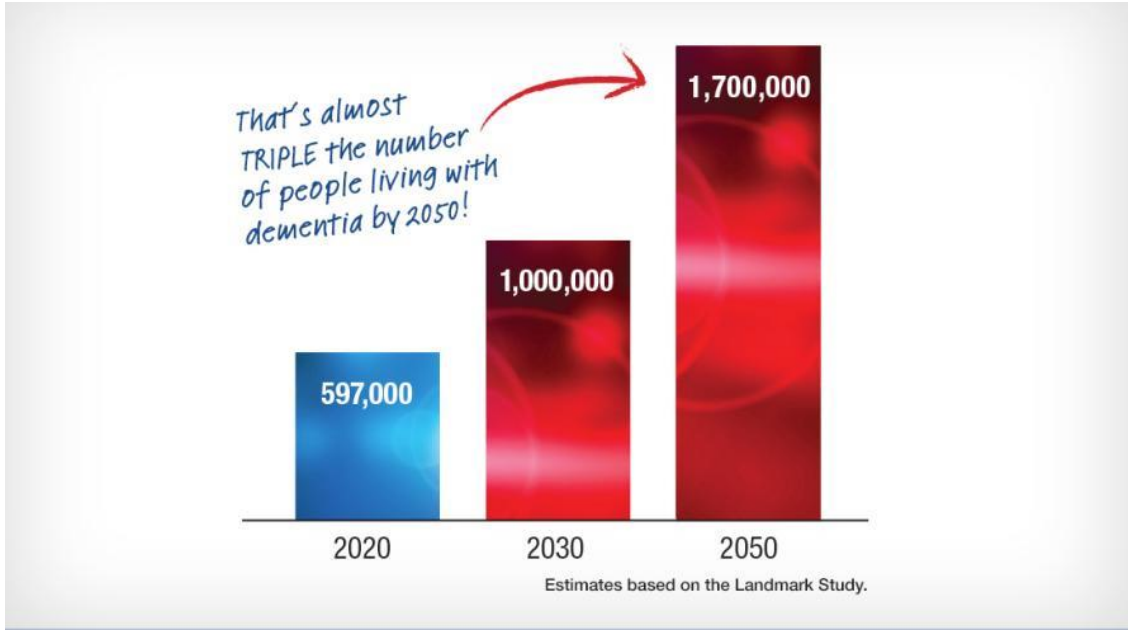
Dementia

569,600

124,000

1 in 5

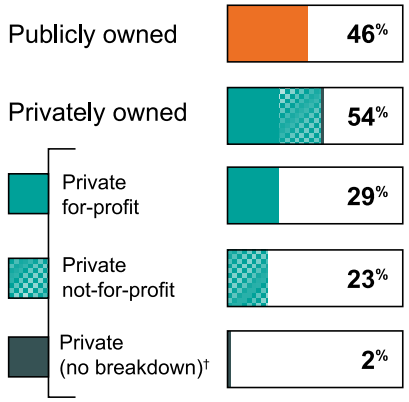
$10.4 billion

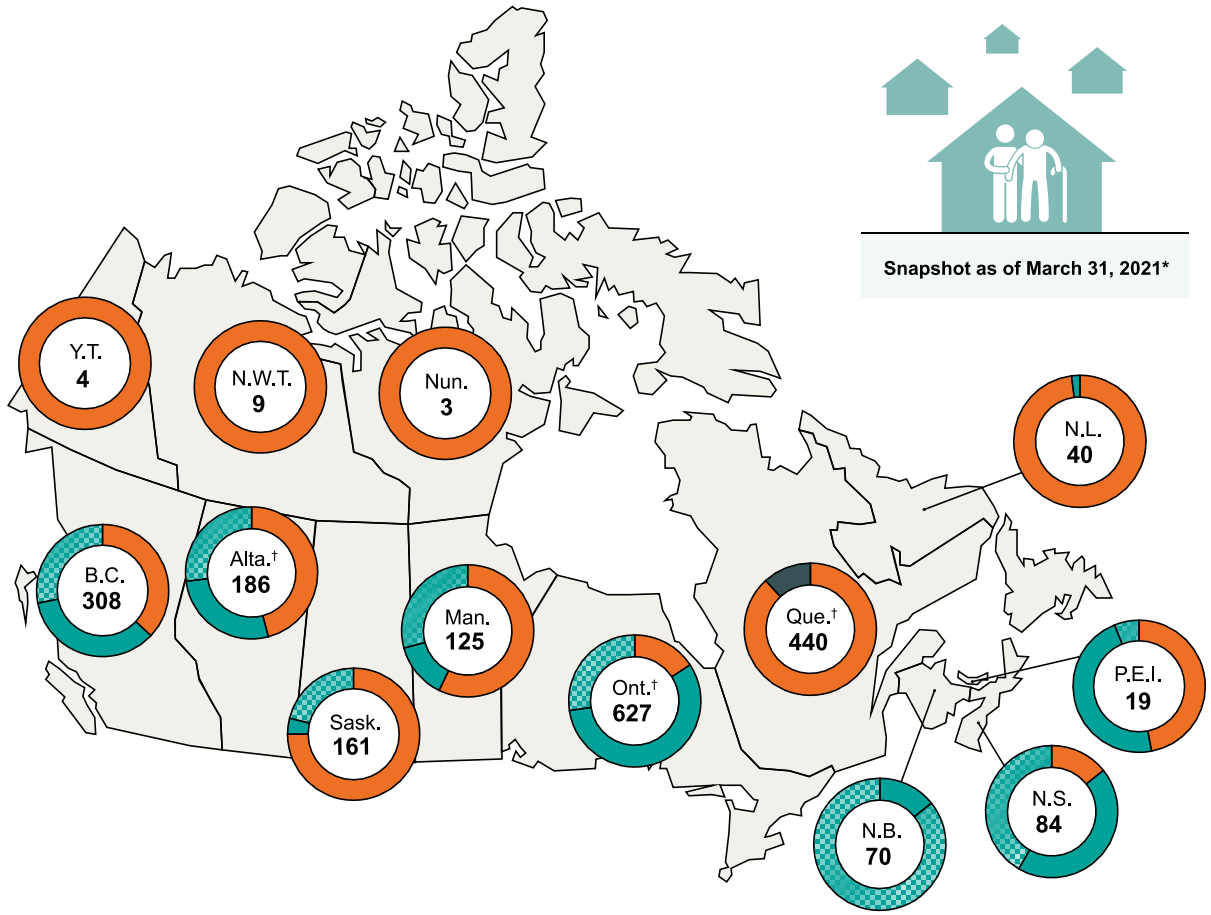


https://alzheimer.ca/en/research/reports-dementia/landmark-study-report-1-path-forward

Canada

Total number of long-term care homes **2,076**





Snapshot as of March 31, 2021*

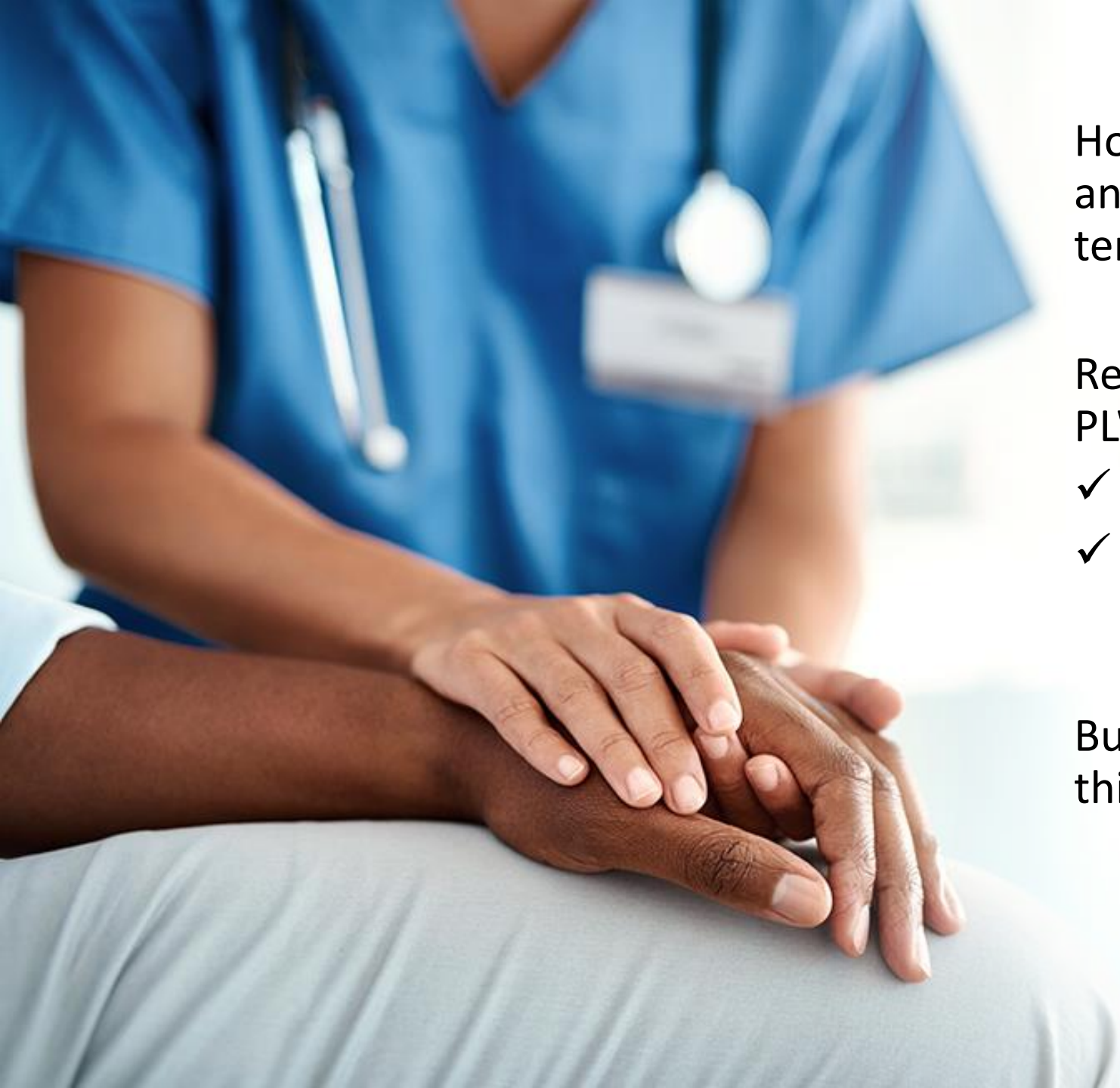
Notes

* Data for all jurisdictions is as of March 31, 2021, except Quebec (as of April 1, 2021) and Alberta (as of February 28, 2021).

† Private for-profit and not-for-profit ownership breakdown information for some long-term care homes in Quebec, Ontario and Alberta was not available at the time of publication.

CIHI

https://www.cihi.ca/en/long-term-care-homes-in-canada-how-many-and-who-owns-them



How to improve the quality of care and quality of life of PLWD in long-term care homes?

Research priorities identified by PLWD include:

- ✓ Care provider education
- ✓ Nonpharmacological management of symptoms

But how to conduct clinical trials in this setting ethically?

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Alzheimer's & Dementia
Translational Research & Clinical Interventions

RESEARCH ARTICLE

Ethical considerations within pragmatic randomized controlled trials in dementia: Results from a literature survey

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Abstract

Introduction: This review aims to describe the landscape of pragmatic randomized controlled trials (RCTs) in the context of Alzheimer's disease (AD) and related dementias with respect to ethical considerations.

Methods: Searches of MEDLINE were performed from January 2014 until April 2019. Extracted information included: trial setting, interventions, data collection, study population, and ethical protections (including ethics approvals, capacity assessment, and informed consent).

Results: We identified 62 eligible reports. More than two-thirds (69%) included caregivers or health-care professionals as research participants. Fifty-eight (94%) explicitly identified at least one vulnerable group. Two studies did not report ethics approval. Of 57 studies in which patients were participants, 55 (96%) reported that consent was obtained but in 37 studies (67%) no mention was made regarding assessment of the patients' capacity to consent to research participation.

Discussion: Few studies reported protections implemented when vulnerable participants were included. Shortcomings remain when reporting consent approaches and capacity assessment.

KEYWORDS
capacity, consent, ethics, research participant

OPEN ACCESS Freely available online

PLOS | MEDICINE

Guidelines and Guidance

The Ottawa Statement on the Ethical Design and Conduct of Cluster Randomized Trials

Charles Weijer[1,2,3]*, Jeremy M. Grimshaw[1,4,5], Martin P. Eccles[6], Andrew D. McRae[1,3,7], Angela White[1], Jamie C. Brehaut[4,8], Monica Taljaard[1,4,8], the Ottawa Ethics of Cluster Randomized Trials Consensus Group[¶]

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The Ottawa Statement on the Ethical Design and Conduct of Cluster Randomized Trials

Ethical issue	Recommendation	
Protecting vulnerable participants	14	Clusters may contain vulnerable participants. In these circumstances, researchers and RECs must consider whether participants additional protections are needed.
	15	When individual informed consent is required and there are individuals who may be less able to choose participation freely because of their position in a cluster or organizational hierarchy, RECs should pay special attention to recruitment, privacy, and consent procedures for those participants.

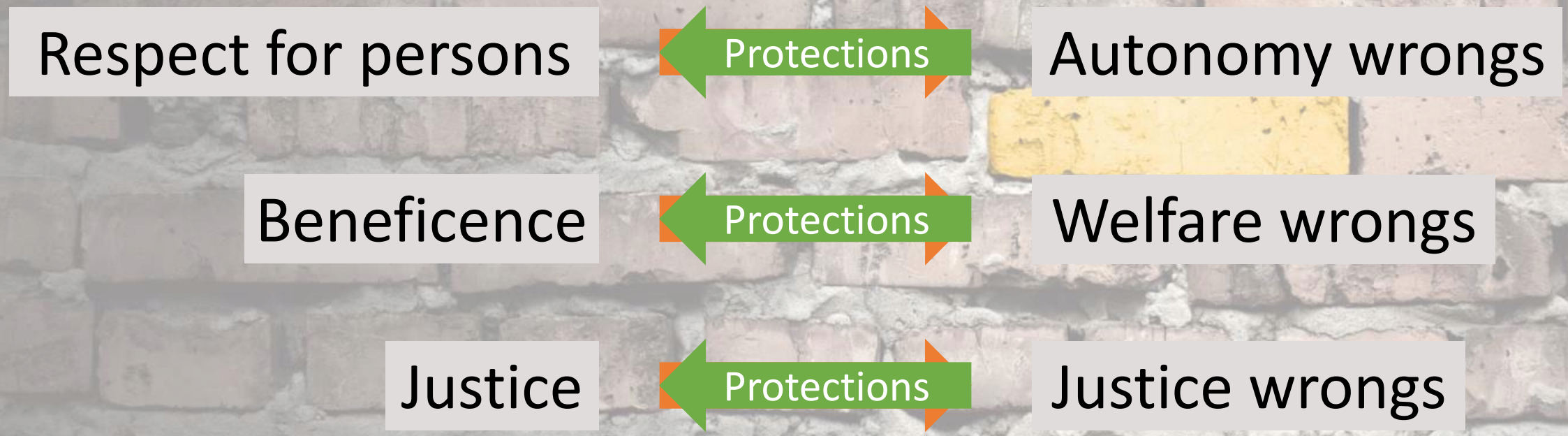
PLoS Med. 2012;9(11):e1001346


Vulnerability

People who are at “an identifiably increased likelihood of incurring additional or greater wrongs” as a result of research participation

Bioethics. 2008 May;22(4):191-202


Respect for persons
Vulnerability
Autonomy wrongs
Beneficence
Vulnerability
Welfare wrongs
Justice
Vulnerability
Justice wrongs


Respect for persons
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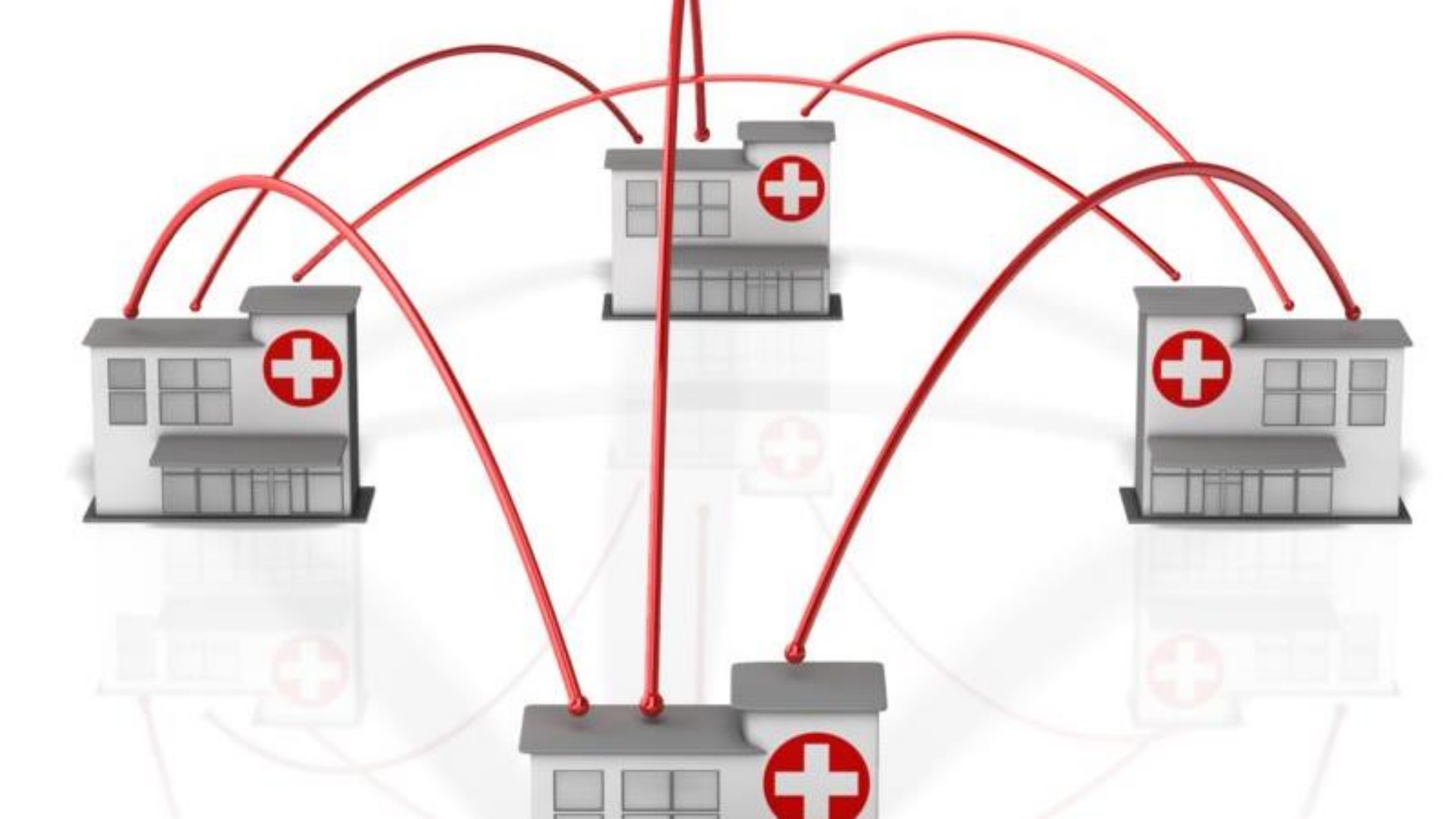


Bath trial

Bath trial

Aim	• Evaluate the effectiveness of the Bathing Without a Battle intervention • Training to teach healthcare providers noncoercive, individualised, person-centered bathing techniques to make bathing safe and comfortable.
Intervention	• Healthcare providers were taught to (1) effectively communicate, (2) understand behavioural symptoms as an expression of unmet needs, (3) respect resident preferences, and (4) ensure the physical environment is safe.
Data collection	• Researchers directly observed each bath and documented physical and verbal aggressive behaviour. • Use of antipsychotic medication on bath days was collected from medical records.
Consent procedures	• Care home administrators sought consent for participation from healthcare providers. • No reported capacity assessments. • Care home administrators sought consent for participation from residents or their family caregiver.

J Am Geriatr Soc. 2014 May;62(5):797-804


Elastic trial
0882
HALF MARATHON
SIDE WEST
0724
0629
HALF MARATHON

Elastic trial

Aim	• Evaluate the effectiveness of the Wheelchair-using Senior Elastic Band intervention • Group exercise sessions designed for wheelchair-using residents.
Intervention	• Group aerobic and resistance exercise sessions led by volunteers, thrice weekly for 6 months. • Additional instructors present during sessions to monitor participants for physical discomfort.
Data collection	• Researchers performed physical assessments, measuring activities of daily living, flexibility, joint range of motion, cardiopulmonary function, and muscle strength and endurance.
Consent procedures	• No reported capacity assessments. • Researchers obtained assent from residents and surrogate consent from their family caregivers.

Am J Phys Med Rehabil. 2016 Nov;95(11):789-799

Managing agitation and raising quality of life (MARQUE) trial

MARQUE trial

Aim	• Evaluate the effectiveness of the MARQUE intervention • Training to teach healthcare providers strategies to manage agitation.
Intervention	• Developed with input from healthcare providers, patients, and community representatives. • Care home staff were trained in the causes and management of agitation and were given feedback on their performance.
Data collection	• Cohen-Mansfield Agitation Inventory and the Neuropsychiatric Inventory at baseline and at 8 months post-training. • Proxy-rated quality of life of participant by interviewing a healthcare provider or a family caregiver.
Consent procedures	• Gatekeeper permission obtained from care home managers. • Researchers obtained consent for participation from healthcare providers. • Capacity assessment using the Mental Capacity Act 2005 criteria. • Sought consent for participation from residents, or surrogate consent from a family caregiver or professional consultee.

Lancet Psychiatry. 2019 Apr;6(4):293-304

https://livewell.care/finding-long-term-care-for-dementia-patients/

1. Inadequate comprehension

Inadequate comprehension

Protections

Bath trial

✓No capacity assessment reported

Elastic trial

✓No capacity assessment reported

MARQUE trial

✓Capacity assessment (Mental Capacity Act 2005 criteria)

Inadequate comprehension

Protections

✓MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR)

- Trained personnel
- 15-30 minutes
- May bias the sample
- May deter large trials

✓Brief screening questionnaire

Inadequate comprehension

<u>Protections</u>

Exceptions:

- ✓Lack of decision-making capacity is an eligibility criterion
- ✓Research procedures very similar to routine medical practice
- ✓Surrogate decision maker
- ✓Assent

https://www.mcknights.com/news/more-than-3000-nursing-homes-earn-top-rating-from-u-s-news-world-report/

2. Inadequate voluntariness

Inadequate voluntariness

Protections

Bath trial

✓LTC home administrators sought consent

Elastic trial

✓Researchers sought consent

MARQUE trial

✓Researchers sought consent

Inadequate voluntariness

Protections

✓Consent sought by researchers (and not LTC home staff)

- "insulate[s] the patient from the hierarchical system"
- Protects against recruitment bias, particularly important in cluster randomized trials

✓Independent patient advocate

https://www.moreability.co.uk/help-advice/2015/09/assisted-showering-solutions-for-long-term-care-settings

3. Invasion of privacy

Invasions of privacy

Protections

✓Stakeholder engagement

- Resident, family, ombudsman…
- Gain insight into privacy norms
- Reduce risk of privacy wrongs
- Ensure design is compatible with the intervention’s setting of intended use.

Invasions of privacy

Protections

Bath trial

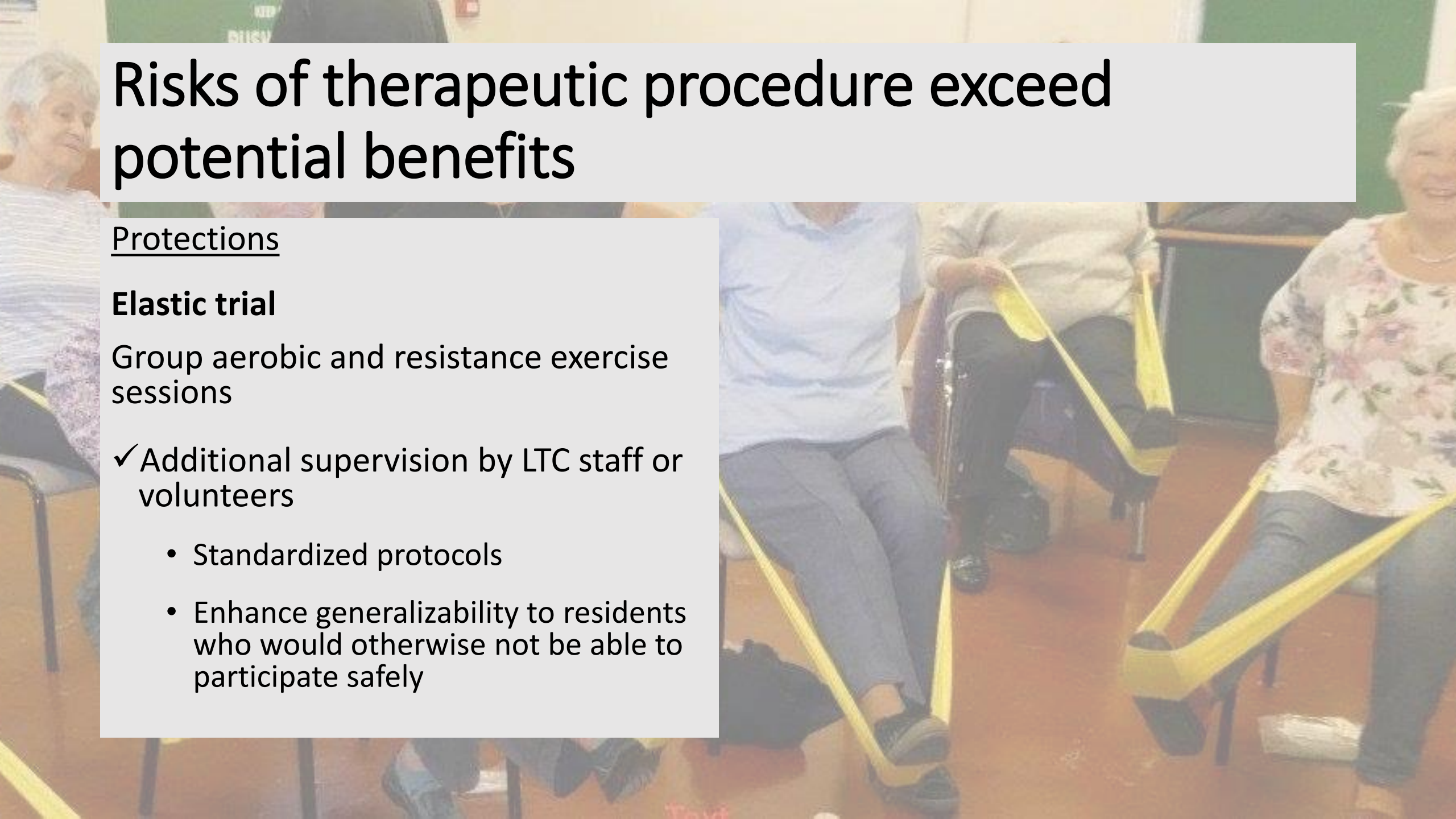
Study intervention and data collection occur in resident's bathroom

- ✓Train LTC staff to observe resident behavior while providing care
- ✓Train researchers to provide targeted aspect of care
- ✓Behavior assessment by listening rather than observing visually

https://sites.google.com/site/stotfoldgoodneighbourgroupinfo/chair-based-exercise-classes

4. Risks of therapeutic procedure exceed potential benefits

Risks of therapeutic procedure exceed potential benefits



Protections

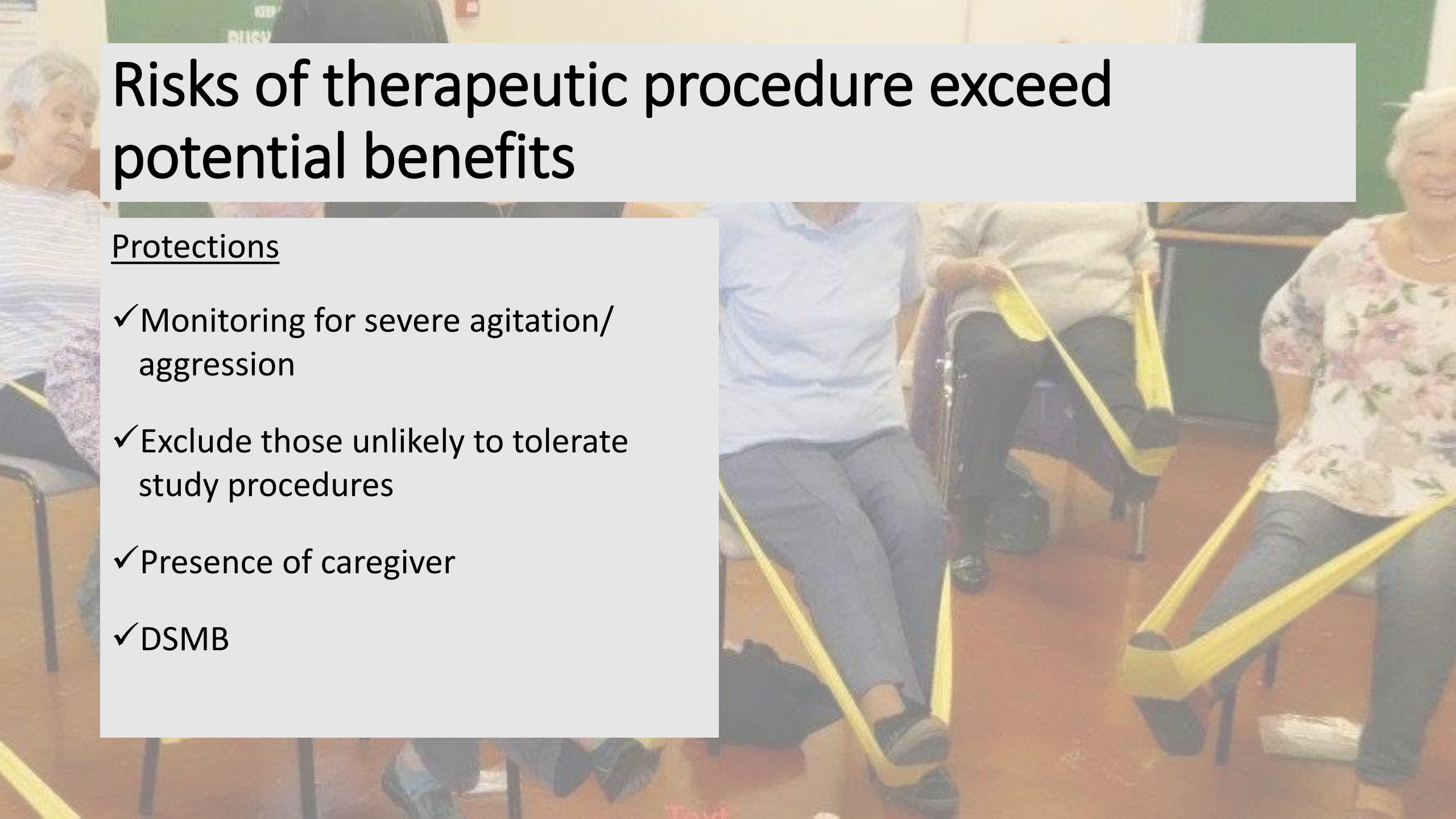
Elastic trial

Group aerobic and resistance exercise sessions

✓Additional supervision by LTC staff or volunteers

- Standardized protocols
- Enhance generalizability to residents who would otherwise not be able to participate safely

Risks of therapeutic procedure exceed potential benefits



Protections

- ✓Monitoring for severe agitation/ aggression
- ✓Exclude those unlikely to tolerate study procedures
- ✓Presence of caregiver
- ✓DSMB

5. Excessive risks of nontherapeutic procedures

https://www.familyfirstfirm.com/what-is-long-term-care-and-who-provides-it/

Excessive risks of nontherapeutic procedures

<u>Protections</u>

- ✓Identify PLWD prone to agitation
- ✓Family members or familiar LTC home staff to fill out questionnaires
- ✓Allows researchers to investigate patient-centered outcomes that might otherwise be inaccessible in PLWD who cannot self-report

https://www.gtaweekly.ca/ontario-supports-training-of-hundreds-of-personal-support-workers/

6. Unjust exposure to burdens of research

Unjust exposure to burdens of research

Protections

- ✓Gatekeepers, including LTC home administrators and medical directors
- ✓Ensure that research activities do not compromise the care provided to all LTC home residents
- ✓Gatekeeper permission

Vulnerability framework

Autonomy wrongs	
Vulnerability	Protections
Inadequate comprehension	✓ Formal capacity assessment ✓ Consent from surrogate decision maker ✓ Participant assent
Inadequate voluntariness	✓ Consent sought by researchers and not LTC staff ✓ Independent patient advocate
Invasions of privacy	✓ Stakeholder engagement ✓ Train LTC staff to collect data ✓ Train researchers to administer care ✓ Limit observation

Welfare wrongs	
Vulnerability	Protections
Risks of therapeutic procedure exceed potential benefits	✓Additional supervision by LTC staff or volunteers ✓Presence of caregiver ✓DSMB
Excessive risks of nontherapeutic procedures	✓Identify PLWD prone to agitation ✓Family members or familiar LTC home staff to fill out questionnaires

Justice wrongs	
Vulnerability	Protections
Unjust exposure to burdens of research	✓ Gatekeeper permission

Research team

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Questions?

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