



STRIDE Study – Glossary of Research Terms

Research Term	Definition	What it means in STRIDE
Adherence	The degree to which participants in a study follow treatment instructions.	
Adjudication	The process of reconciling various sources of information to determine what happened to patients in the study.	In STRIDE, we need to adjudicate the primary outcome – serious fall injuries – because there are multiple sources of information about the primary outcome (participant report, hospital and clinic records, Medicare billing codes). None of these sources is perfect in and of itself.
Adverse event (AE)	An unfavorable change in the health of a participant that happens during a clinical study. This change may or may not be caused by the intervention /treatment being studied.	
Algorithm	A diagnostic algorithm is a step-by-step method for making a diagnosis using a combination of symptoms, signs, or test results.	The STRIDE intervention uses algorithms to identify whether a participant has these risk factors for falls: 1) changes in leg strength, balance, and/or walking, 2) medications, 3) postural hypotension (blood pressure drop that happens when you stand up from sitting or lying down that may cause dizziness), 4) feet/footwear, 5) home environmental hazards, 6) risk of osteoporosis (weak bones), 7) vitamin D supplements, 8) vision problems.

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Assessment	Assessment refers to the collection of data to describe or better understand an issue.	The STRIDE Recruitment and Assessment Center (RAC) collects data by conducting phone interviews with study participants. There is an initial (baseline) interview, followed by regular interviews every 4 months.
Baseline characteristics	Descriptive information about the participants in a study collected at the beginning of the study. These data include demographics, such as age, sex/gender, race and ethnicity, and study-specific measures.	
Bias	When error is introduced by encouraging one outcome or answer over others. In clinical studies, bias is controlled by blinding and randomization .	
Blinding/masking	A way to keep participants and researchers from knowing who is getting the treatment or test being studied.	
Centers for Medicare and Medicaid Services (CMS)	The Centers for Medicare & Medicaid Services (CMS) is a federal agency within the United States Department of Health and Human Services (HHS) that administers the Medicare program and works in partnership with state governments to administer Medicaid.	STRIDE received approval to use CMS data to help adjudicators determine if a patient experienced a serious fall injury.

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Clinical trial	A research study to determine whether an intervention is safe and effective.	
Cluster randomization	In cluster randomized studies, groups, for example, primary care practices - rather than individuals - are randomly assigned to one of two or more treatments.	STRIDE is a cluster randomized clinical trial . Primary care practices were allocated to either the intervention or the control group .
Control group	The control group is the group in a study that does not receive the intervention /treatment.	
Data Safety Monitoring Board (DSMB)	An independent committee of experts responsible for reviewing research study data on an ongoing basis to ensure the safety of study subjects and the accuracy and consistency of the data.	
Dissemination	The process of identifying target audiences and tailoring communication strategies to increase awareness and understanding of evidence, and to motivate its use in policy, practice, and individual choices.	Target audiences for STRIDE include: older adults with fall risk and their caregivers, health care providers (doctors, nurses, therapists), researchers, policy makers.

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Electronic Health Record (EHR)/Electronic Medical Record (EMR)	An electronic (digital) collection of medical information about a person that is stored on a computer. An electronic health record (EHR) includes information about a patient’s health history, such as diagnoses, medicines, tests, allergies, immunizations, and treatment plans. Electronic health records can be seen by all healthcare providers who are taking care of a patient and can be used by them to help make recommendations about the patient’s care. Also called electronic medical record (EMR).	Electronic Health Records are a source of information to help adjudicators determine if a patient experienced a serious fall injury.
Enrollment	Enrollment is the act of including a participant in a study. Participants should be included only after it has been confirmed that all the eligibility criteria have been met. Enrollment should occur before assignment to a treatment group.	Patients who received a STRIDE recruitment packet and did not return the opt-out post card were called for possible enrollment by a study staff member at the Recruitment and Assessment Center (RAC).
Falls Care Manager (FCM)	Falls Care Manager is a term related specifically to the STRIDE Study and not a general research term.	The Falls Care Manager (FCM) is a nurse who is responsible for providing the STRIDE intervention . The FCM works in collaboration with the primary care physician.

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Follow-up	Follow-up is the process of monitoring participants in a study to measure outcomes and collect other data. Follow-up can last for days or years. Longer follow-up is desirable to measure long-term effects.	In STRIDE, people are followed from randomization to the end of the study. The follow up is a minimum of 24 months and a maximum of 44 months.
Inclusion/Exclusion criteria	Factors that allow someone to participate in a clinical trial are inclusion criteria. Those that do not allow participation are exclusion criteria.	In STRIDE, the main inclusion criteria are: community-living persons, 70 years or older, who are at increased risk for serious fall injuries.
Informed consent	The informed consent document explains the purpose of the research study, potential risks and benefits, and participant’s rights and responsibilities.	
Institutional Review Board (IRB)	A group that follows federal regulations, state laws, and institutional policy to review, monitor, and approve research to protect the ethical rights and privacy of the subjects involved.	
Intent to treat analysis	Analysis of clinical trial results that includes all data from participants in the groups to which they were randomly assigned even if they never received the treatment or withdrew from the study.	

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Intervention	A process or action that is the focus of a clinical study. Interventions can include drugs and medical devices/procedures, as well as other approaches, such as education or modifying diet and exercise.	STRIDE intervention: Falls Care Manager (FCM) performs fall risk assessments , and together with the patient develops individualized fall care plans.
Intervention group	The intervention group is the group in a study that receives the intervention /treatment.	
Multifactorial intervention	An intervention involving several factors.	STRIDE intervention has 5 major components: 1) assessment of 8 fall risk factors; 2) explanation of assessment results to patient/caregiver; 3) creation of fall care plan; 4) implementation of fall care plan; 5) ongoing monitoring and re-assessment.
Multisite study	A study in which several sites (e.g. hospitals or primary care clinics) work together.	STRIDE is a multisite study - 86 practices in 10 health care systems across the country.
Outcome measure	A measurement that is used to determine the effect of an intervention /treatment on participants.	
Patient centered outcomes research	Research that helps people and their caregivers communicate and make informed healthcare decisions, while allowing their voices to be heard in assessing the value of healthcare options. This research answers patient-centered questions.	STRIDE Study is patient centered outcomes research. The research is jointly funded by PCORI (Patient Centered Outcomes Research Institute) and NIH (National Institutes of Health).

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Patient engagement	Involvement of patients and other stakeholders throughout the planning, conduct, and dissemination of a study.	STRIDE has a National Patient Stakeholder Council (NPSC) and 10 Local Patient Stakeholder Councils.
Peer review	A process through which articles or papers submitted for publication are reviewed by others (peers) knowledgeable in fields covered by the paper, to assist journal editors to decide whether the paper should be accepted for publication.	As a PCORI (Patient Centered Outcomes Research Institute) funded study, STRIDE will undergo additional peer review. The peer review of the PCORI Final Research Report includes patient input.
Pragmatic trial	A study designed to assess the effects of a treatment given in the circumstances of everyday practice. Studies to assess the effects of treatments can be designed to address one of two questions: "Can this treatment work, given ideal circumstances?" or "Does this treatment work, in the messy circumstances of the real world?" Those that address the second question are pragmatic trials.	STRIDE is a pragmatic trial.
Primary outcome measure	The planned outcome measure that is the most important for evaluating the effect of an intervention /treatment.	Primary outcome in STRIDE: serious fall injuries.
Principal Investigator (PI)	The lead researcher and primary contact for the project.	Dr. Shalender Bhasin (Brigham and Women’s Hospital), Dr. Thomas Gill (Yale University), and Dr. David Reuben (UCLA) are the Principal Investigators for STRIDE.

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Protocol	The written description of a clinical study. It includes the study's objectives, design, and methods.	
Protocol amendment	Changes or clarifications made in writing to the original protocol . These changes must be approved by the Institutional Review Board (IRB) .	
Randomization	A process by which research participants are assigned, by chance, to groups receiving or not receiving the treatment or test being studied.	
Recruitment	The overall process of attracting and selecting suitable candidates for a research project.	Patients 70 years and older who screened positive for fall risk were identified at the 86 STRIDE primary care practices. These patients were sent a recruitment packet by the STRIDE Recruitment and Assessment Center (RAC).
Retention	The overall process of keeping participants enrolled in a study for its duration.	
Sample size	The number of participants to be studied. The sample size should be big enough to have a high likelihood of detecting a true difference between two groups.	The target sample size in STRIDE was 5,322; The actual number enrolled was 5,451.

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Secondary outcome measure	An outcome measure that is not the primary focus for evaluating the effect of an intervention but is still of interest. Most clinical studies have more than one secondary outcome measure.	Secondary outcomes in STRIDE: number of falls, number of all fall injuries, and measures of well-being (concern for falling; anxiety and depressive symptoms; physical function and disability).
Serious adverse event (SAE)	Any adverse event that is fatal, life-threatening, permanently disabling, or which results in hospitalization, initial or prolonged.	
Short Physical Performance Battery (SPPB)	A test to measure lower extremity functioning in older persons. It assesses walking speed, standing balance, and sit-to-stand performance.	
Statistical power	The probability (likelihood) that a study will detect a "statistically significant" difference between the effects of the treatments being compared. The sample size for the study is often chosen in the hope of giving the trial the desired statistical power.	
Study arm	Any of the treatment groups in a randomized trial. Most randomized trials have two arms.	
Usual care	The usual health care provided to patients.	The control group in STRIDE receives enhanced usual care, with clinicians and patients receiving evidence-based information on falls prevention.

Source material for definitions:

ClinicalTrials.gov Glossary of common site terms <https://clinicaltrials.gov/ct2/about-studies/glossary>

CenterWatch Clinical trials glossary <https://www.centerwatch.com/health-resources/glossary/>

GET-IT glossary <http://www.getitglossary.org/>

Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard <https://mrctcenter.org/health-literacy/tools/overview/glossary/>

PCORI Glossary <https://www.pcori.org/glossary>

NIH Glossary of common terms <https://www.nih.gov/health-information/nih-clinical-research-trials-you/glossary-common-terms>

University of Michigan Library Plain language medical dictionary <https://www.lib.umich.edu/medical-dictionary/>