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Partnering with Youth, Families, & Patients in Research

A Standard of Compensation

for Youth, Family, and Patient Partners 2021

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Portions of this document are adapted from "Budgeting for Involvement," Simons, L., Kabir, T., & Cartwright, J. (2013) with permission from the United Kingdom National Institute for Health Research.

About this Resource

This standard is created by CYSHCNet, a national research network focused on children and youth with special health care needs and their families. We believe that engaging youth, families, and patients as full partners in the research process makes research better. The recommendations outlined in this guide are designed to help youth, families, and patients who participate as partners on a research team. It includes information on what support, compensation, and reimbursement you might expect to receive as well as possible roles and responsibilities that you might undertake. These recommendations might need to be adapted, depending on the particular role that you are working in, such as quality improvement or evaluation.

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Background: The role of Youth, Families, & Patients in Research

The role of youth, families, and patients in designing, carrying out, and evaluating research studies has been growing. Unfortunately, they have not been recognized as they should be.[1] Now, researchers and the organizations that pay for research studies recognize the important role of youth, families, and patients as research partners. **"Family-centered care"** includes involving youth, families, and patients on research studies as research partners. Rather than doing things to or for them, the youth, families, and patients become members of the research group. By partnering with youth, families, and patients on studies, research teams show that they appreciate the knowledge and experience that youth, families, and patients have.[2–4]

This type of research collaboration is supported by family and community organizations like Family Voices, payers like the Patient-Centered Outcomes Research Institute (PCORI), and federal agencies like the Health Resources and Services Administration's (HRSA) Maternal and Child Health Bureau.[5] Organizations such as these believe that engaging youth, families, and patients in research studies as partners makes the research more meaningful to them and improves the quality of the research[6]. Furthermore, many payers now require that youth, families, and patients participate in planning and carrying out research projects.[7,8]

> *"Making patients and their families truly the force that drives everything else in health care is perhaps the most revolutionary tool of all."* 9(pxxii)

As part of the research team, you bring your first-hand experience and the experiences of many other families. These experiences help researchers design health-related research that is important to youth, families, and patients. As a research partner, you also help researchers understand the results of a study, and put the results into practice in the real world.

You bring the perspective of someone very close to, but not a part of the health care system. You are an expert in navigating the parts of the health care system that are important to you or your child. You know how the system really works as opposed to how it was designed to work.

About CYSHCNet

CYSHCNet National Research Network was founded in 2017 as a cooperative agreement with HRSA's Maternal and Child Health Bureau to research health systems that support CYSHCN, their families, and providers.

A core value of CYSHCNet is to include the knowledge, expertise, and experience of youth, families, and patients in the research process. Youth, family, and patient partners are engaged in all aspects of CYSHCNet projects from planning, through data collection, to reporting and dissemination of research outcomes.

A family-centered approach that utilizes the valuable insights of family caregivers, youth, and patients enhances the research process and outcomes for CYSHCN and their families.[4]

A core value of the CYSHCNet is to include the knowledge, expertise, and experience of youth, families, and patients in the research process.

This Guide

Recognizing that youth, family, and patient partners bring different skill sets and interests to a project,[10] this guide provides recommendations to youth, families, and patients for collaborating with researchers on studies and outlines fair compensation for your work. Being a partner on the research team from the beginning of a study ensures that you have more say in the study than participating on a community advisory board or other type of community engagement activity. But regardless of how you partner with a research team, fair compensation for the work that you do as part of the research team is essential.

Many payers are asking that studies include youth, family, and patient partners in various roles such as advisory boards, consultants, partners, co-researchers, and even staff.[5] While more researchers are recognizing the value of working with youth, family, and patient partners, there has not been much information about how to compensate youth, families, and patients for their contributions to research[11,12].

CYSHCNet requires that every research project engage at least one youth, family, and/or patient as a team member. We strongly recommend, however, that research projects have two or more youth, family, and/or patient partners.

Youth, families, and patients play many roles in research and need to be compensated appropriately for their time and expertise. Rather than a "one size fits all" payment of gift cards or bus fare, youth, family, and patient partners should be compensated based on their level of responsibility, time spent on the project, and contribution to the project.[10,13,14] Unique circumstances for each research partner requires that the principal investigator (PI) and the research team be thoughtful about the method and timing of compensation.[13]

For example, additional income may hurt a family's eligibility for Medicaid or other financial programs that provide critical supports and services to patients and families. *It is important to have a discussion with the research team about any financial restrictions before the beginning of a project so that these situations can be addressed*.

In this guide, we discuss compensation and include recommendations in Section 3.

1. Introduction: The Standards of Compensation Guide

1.1 Who Is This Compensation Guide For?

This guide focuses on the needs of youth, family, and patient partners, but is also useful for

- Researchers
- Funders (or payers)
- Evaluators
- Grant Reviewers

This compensation guide applies to youth, family, and patient leaders who work as partners on research studies and who are not employees of the researchers' organizations.

1.2 Aims of the Standard of Compensation Guide

This guide outlines the CYSHCNet policy on payment for youth, family, and patient partners who work on research projects in any capacity. However, the recommendations can be applied to any research setting where youth, families, or patients are key members of the research team. This guide does not include recommendations on compensation for study participants such as interviewees.

This Guide:

Explains levels of participation of youth, family, and patient partners in research projects	Presents a sample budget
Explains compensation and expenses for youth, family, and patient partners	Suggests ways to work with outside organizations such as community-based groups who can be very effective partners in recruiting and supporting youth, family, and patient partners (see Appendix A for a list of some community-based organizations).

1.3 What is "Active Engagement" in Research?

Active engagement by youth, family, and patient partners is defined as "research being carried out *with* or *by* youth, families, and patients rather than *to, for,* or *about* them – "nothing about us without us".[15] This includes, for example, youth, family, and patient partners working with funders to prioritize and design research projects, providing advice about or actively recruiting participants, helping to develop materials, carrying out aspects of research such as conducting interviews with study participants, among other activities.

Community or youth, family, and patient partners can include:

- Patients and potential patients;
- People who provide care or support to patients on an informal basis;
- Parents or guardians of patients;
- Adults with health conditions beginning in childhood;
- Individuals who may be targeted by public health or health promotion initiatives;
- Community-based organizations led and staffed by patients or families such as Family Voices and Family-to-Family Health Information Centers.

Taking part in a research study as a study participant is not "active engagement". This guide highlights the need for youth, families, and patients to contribute fully on research teams, not as study participants. For information on how to become a study participant, visit www.researchmatch.org.

Active Engagement means a partnership between youth, families, patients and researchers in every aspect of the research process, rather than just participation of people as subjects of research.

Active engagement may include:

- Partnering in the designing, writing, and reviewing of a research proposal;
- Participating in meetings about research at every stage;
- Preparing for meetings and other activities by reading relevant documents;
- Participating in training events, receiving support and mentoring around research terms and processes;
- Interviewing participants or leading a focus group;
- Co-production of reports, articles, and other dissemination materials;
- Presenting research findings at a conference;
- Sharing findings with communities and patients and their families.

1.4 Increasing Engagement of Diverse Youth and Family Partners

It is important that youth, family, and patient partners are representative of the populations being researched. Diversity does not mean only racial and ethnic diversity, but also diversity in socioeconomic status, education, geography, rural/urban, culture, nationality, language, religion, and other aspects of the human condition.[17] We encourage youth, families, and patients from diverse backgrounds to become research partners.

1.5 Levels of Youth, Family, and Patient Partners' Participation and Compensation in Research

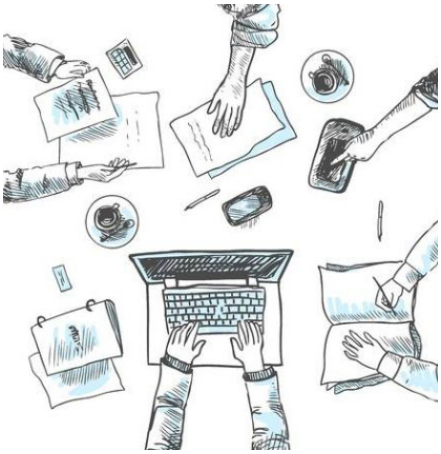
The chart on the following page provides guidance on the levels of participation for youth, family, and patient partners in research. Compensation should be flexible enough to consider each youth, family, and patient partner's circumstances; the amount of money available within a grant; expertise of youth, family, and patient partners; and the specific roles requested of the youth, family, and patient partners.

Youth, family, and patient partners serving in identical roles (for example, serving on a committee) should receive the same compensation as everyone else serving in that role. You should discuss your individual circumstances with the research team to deal with any barriers that may deter you from participating fully in the study.

EXAMPLE LEVELS OF PARTICIPATION IN RESEARCH		
Category of Participation	**Expectations**	**Type/Method of Compensation**
On-going and consistent team member	• Youth, family, and patient partners have an on-going relationship with the project, but are not employees of the organization. • Having an "on-going relationship" means that s/he is participating on a regular basis, which may include attending regular meetings, engaging in scheduled tasks such as survey development, data collection, participant recruitment, and others. • youth, family, and patient partners may work on an hourly basis or on contract and may require a 1099 form, scope of work, or other documentation for the organization.	A contract is appropriate, based on an hourly rate or on a per-job basis.
Advisor	• Youth, family or patient partner has time-limited contact with the project, for example, reviewing survey questions, wording of documents, transcribing or translating a document, conducting key informant interviews, participating in one-time or periodic Advisory Committee meetings. • Youth, family, or patient partner acts as a facilitator or co-facilitator of a focus group. • Youth, family, and patient partners may be part of a group of individuals serving in similar roles, such as on an Advisory Committee. In this case, compensation should be consistent for all members of the group doing the same job.	A stipend is appropriate.
Speaker	• Youth, family, or patient partners invited to speak at a national or local conference or meeting and assist with dissemination of material related to the research project.	A stipend or honorarium is appropriate
Staff	• Youth, family, or patient partner who is hired to work on tasks that are a core function of a project and is a regular employee of the organization, even if the employment is temporary in nature. • Role may focus on family outreach (recruiting, interviewing, direct family contact). • Performs functions commensurate with expertise, but brings the perspective of lived experience – this could be at any level from research assistant to PI. • Can facilitate relationships with external family partners, but does not replace the role of external youth, family, and patient partners. • Expect this role to be on-going throughout the project.	A paycheck is appropriate.

2. Payment and Incentives: Fees to Individuals

Payment for your work on the research team should recognize your time, skills, and expertise. These payments may be in the form of cash or check, gift cards, or in-kind; the type of payment will depend on your individual needs and circumstances. The compensation rate offered will depend on a number of factors including expertise, expected time commitment, and level of responsibility.



It is a best practice to develop a contract or scope of work (SOW) that outlines your duties and compensation. You may be paid by a set fee based on a contract, by the hour, or by the task. CYSHCNet recommends that payments begin at a rate of $25 per hour with a $100 minimum payment.

This rate is similar to the average hourly rate for an entry-level research assistant[18–20] in the United States and includes an increase for lived experience. This rate would not include incidental expenses for childcare, transportation, or other expenses that you might incur. It is helpful to establish a contract with the research team that is based on the hourly rate or on a monthly/periodic retainer.

The following questions may be helpful in understanding the rate that is offered to you.

- What level of skills, expertise, and experience is required for the project?
- What are the time commitments involved in the role (including preparation, reading, travel, meetings, etc.)?
- What is the level of responsibility required?
- What training outside of specific project training is required?

2.1 How Will you be Paid?

Organizations have different policies or practices for paying partners on a one-time or on-going basis. You should ask what requirements an organization has for processing payments. You may have to fill out certain forms that establish you as a contractor with the organization. Other requirements such as providing a scope of work (SOW) can be handled by the research team.

It usually takes several weeks for payments to be processed, depending on each organization's requirements, work load at the time, and the type of payment, such as check, gift card, expense reimbursement, etc. If you have been hired as staff, payments will be made the same as to any other employee.

CYSHCNet recommends that payments for begin at a rate of $25 per hour with a $100 minimum payment.

2.2 Covering your Expenses

If you have questions about whether any expense is covered, you should ask the research team before you spend any money.

Reasonable and necessary expenses will usually be covered either by reimbursement to you or by paying the expenses directly to the vendor. A vendor is a person or company that sells a product or service such as an airline, childcare provider, or registration for a conference.

- Reimbursement: For out of pocket expenses that you have already incurred, you should provide **original receipts** for each item that you have paid for.
- Direct Pay: The research team will pay for expenses directly to the vendor, for example, travel tickets or hotel accommodations.

2.2.1 Expenses Typically Covered

Travel

Expenses may include public transit fares, mileage, or airfare as appropriate. Most organizations have a rate for mileage reimbursement and may also have travel agencies that they use for air travel. Also included may be parking fees and additional expenses that you have as a result of travel. If you require a personal assistant, the cost for travel for that person will be included. You should have the research team book your travel so that you will not have out-of-pocket expenses.

Conference and Meeting Fees

You may be asked to attend a conference as a presenter or attendee. Costs may include travel, hotel, conference fees, and food. Other costs may be incurred, depending on the activities in which you participate.

Overnight Accommodations

If you are traveling a long distance or participating in a conference or other meeting over several days, you may need overnight accommodations. The institution may have a special rate for hotels and a preferred travel agent. You should let the research team know if you need overnight accommodations so that hotels can be booked early for the best rates. You should have the research team book your hotel so that you will not have out-of-pocket expenses.

Food

Meals during travel or long meetings will usually be covered using the institution's per diem rate. Usually travel days are covered at a lower amount than non-travel days.

Childcare or Caregiving

You may need someone to care for a child, youth, or adult during the time you are working on the project. The cost for caregiving will vary depending on the type of care needed. You should discuss with the research team what types of caregiving you need and be prepared to provide evidence of the cost, such as an invoice.

Accommodations and Personal Assistants

If you need support for impairments such as hearing or mobility you should discuss with the research team what types of costs to anticipate and whether the organization can pay the caregiver directly. Occasionally, state benefit programs will help cover the cost of a personal assistant. See Appendix for some organizations that can provide information about paying for personal assistants.

4.5 Other Costs

- Background Checks
- Medical Checkups or Vaccinations
- Institution-required Trainings

Depending on your role, you may be required to have background checks, vaccinations, or other services that ensure the safety of study participants. If you are working in a hospital setting, for example, the hospital may require certain vaccines, background checks, and specific institutional training such as HIPPA certification.

2.3 Taxes, Insurance and Benefits

Fees paid to you may be subject to tax and may be reportable to agencies that handle any benefits you may have. You should check with the agencies that provide your benefits to find out whether any income that you receive will impact your ability to receive benefits. You are responsible for calculating whether you are able to accept payments for your participation in the study.

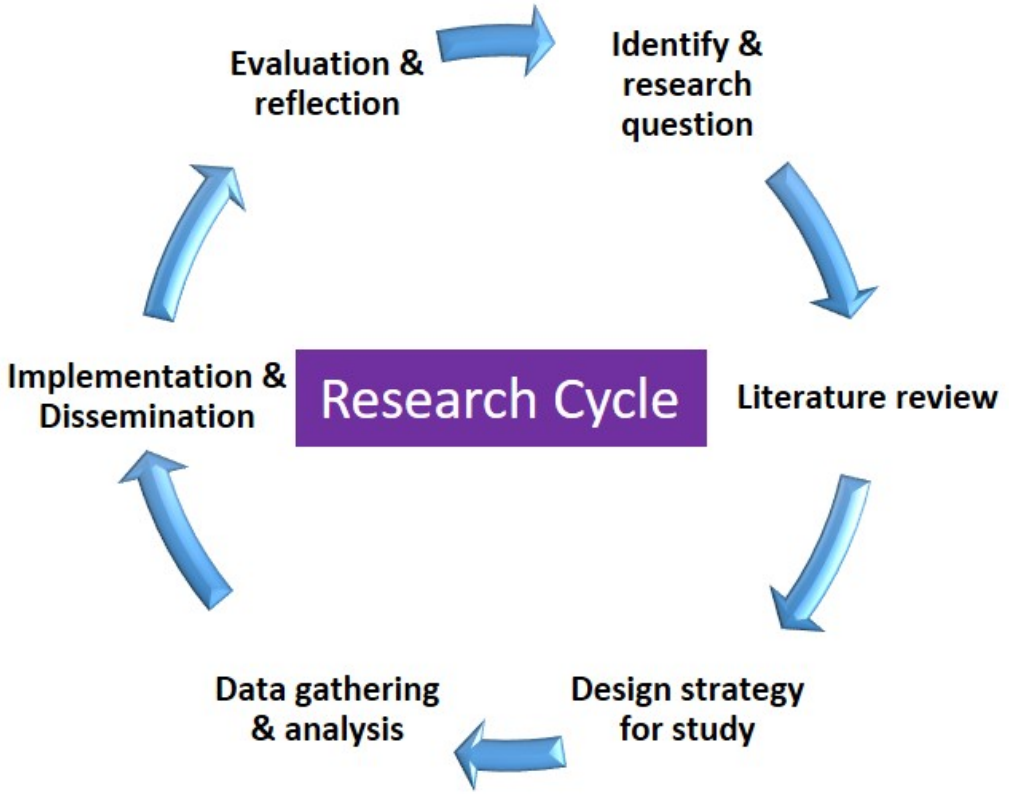
Reimbursements for expenses are typically not included as income; however, you should verify whether reimbursements will count toward your income. Research staff are unable to offer advice on how payments may affect your benefits. To get information about reimbursements, you should check with the specific benefits office such as Medicaid, SSI, TANF, or others.

You can get general information about means-tested benefits at Families USA (also see appendix for their website).

2.4 What a Budget Might Look Like

This section presents a sample budget and a discussion of how you might be engaged in a study. While you can begin at any point in a study, we suggest that research teams engage youth, family, and patient partners as early as possible in the planning of a study.

Where in the Research Cycle Might You Become Engaged?



This diagram is adapted from the INVOLVE Briefing notes for researchers (2012)
www.involve.nihr.ac.uk/posttyperesource/where-and-how-to-involve-in-the-research-cycl

This diagram will help you think through your process.

2.4.1 How Much Does a Study Cost?

Below is a sample table that helps researchers estimate expenses for youth, family, and patient partners. The actual cost depends on the individual cost of each item as outlined in the example below.

SAMPLE BUDGET			
Expense Type	Quantity	Estimated cost each	Total
Payment and incentives			
Salary or stipend (Six 1-hour meetings (2 in-person), 3 hours prep time, 6 hours follow-up time, one half-day local conference)	19 hours	$25 - $50	$475 - $950
Expenses for youth, family, and patient partners			
Travel from home to meeting (for 2 meetings + 1 local conference)	45 miles	$.54/mile	$25
Childcare or caregiver based on child needs and local costs ($20 per meeting lasting 1 hour each + 1 hour travel time X 2 meetings)	8	$20	$160
Food	n/a		
Personal assistants	n/a		
Overnight accommodations	n/a		
Engagement activities			
Finding youth, family, and patient partners collaborators (staff time)	n/a		
Training costs for partners – Fyreworks, PORCCH or PCORI training modules to be done at partners' own pace, but completed within 60 days	5 hours	$25	$125
Conference registration for local conference	1	$150	$150
Staffing	n/a		
Other costs			
Background checks and medical checkups or vaccinations (background check required by hospital)	1	$160	$160
Translation or interpretation	n/a		
TOTAL			**$1,095 - $1,570**

3. Training and Orientation

Training and orientation will usually be required for youth, family, and patient partners. You will need to understand the project, your role, and the roles of others, including the principal investigator, research assistants, and other members of the research team as well as basic information about teams and processes.

You may also need training that is specific to your role. At the end of this guide is a comprehensive glossary of research terms that we hope will be helpful as you embark on your project.

Connecting with a family-based or community organization such as Family Voices can assist with orienting you and the research team. Use the sample template below to list the basic engagement activities that you should know about. There may be other items and activities that are not listed. You should ask the research team about the specific roles and responsibilities that you will have.

Research studies often encounter changes to the protocol, so your roles and responsibilities may change during the course of a study. The timeline of a study may also change if, for example, the study is cut short or if it goes to a second phase. You will want to be aware of potential changes in the study and consult with the research team.

Training is important even if you are a seasoned youth, family, or patient partner. Each study is different and each research team is different. Training may involve getting to know the team and understanding the study or it may involve more formal training such as a class in research methods. You should feel well informed about the study and ask questions about anything that you don't understand or that needs clarification.

Conclusion

Working as a youth, family, or patient partner on research projects is a rewarding experience that pays dividends in terms of the quality and applicability of the research findings. Youth, family, and patient leaders are an important part of research teams because studies show that engaging them makes research better and more meaningful to all stakeholders.

Compensating youth, family, and patient partners fairly for their expertise, lived experience, and work on a project shows a commitment to excellence in research and helps ensure that the findings represent the population being studied. We hope that this guide will help you get the most out of your engagement in a research project. For questions or more information about CYSHCNet, please visit our web site at www.CYSHCNet.org.

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Appendix

Family & Community Organizations	
FAMILY ORGANIZATIONS	PERSONAL ASSISTANTS INFORMATION
Family Voices www.FamilyVoices.org The ARC www.thearc.org Institute for Patient- and Family-Centered Care www.ipfcc.org Hands and Voices www.handsandvoices.org Parent to Parent www.p2pusa.org National Alliance on Mental Illness (NAMI) www.nami.org/Find-Support/NAMI-Programs/Nami-Family-Support-Group Genetic Alliance www.geneticalliance.org Families USA http://www.FamiliesUSA.org	Special Needs Answers https://specialneedsanswers.com/personal-care-assistants-can-offer-much-needed-help-to-families-with-special-needs-children-15859 Funding Options for Personal Assistance Services https://www.dol.gov/odep/research/FundingOptionsPersonalAssistanceServices(PAS).pdf

Glossary of Research Terms

Abstract
This is a brief summary of a research study and its results. It should tell you why the study was done, how the researchers went about it, and what they found.

Action research
Action research is used to bring about improvement or practical change. A group of people who know about a problem work together to develop an idea about how it might be resolved. They then go and test this idea. The people who take part in the testing provide feedback on their experiences. They may also identify further actions that need to be researched and tested. This cycle of developing solutions and testing them is repeated until the problem has been solved. This is most similar to quality improvement (QI) and its academic cousin, QI research.

Adverse event
An unfavorable outcome that occurs during or after a surgical or diagnostic procedure, or the use of a drug or other intervention, but is not necessarily caused by it.

Adverse Reaction (AR)
Any untoward and unintended response to a drug related to any dose administered.
Comment: All adverse events judged by the reporting investigator as having a reasonable causal relationship to a medicinal product would qualify as adverse reactions. The expression 'reasonable causal relationship' means to convey, in general, that there is evidence or argument to suggest a causal relationship.

Advisory group (steering group)
Many research projects have an advisory group (or steering group). The group helps to develop, support, advise, and monitor the project. The group often includes people who use services, caregivers, researchers, and other health and social care professionals, who can provide relevant advice.

Analysis (data analysis)
Data analysis involves examining and processing research data, in order to answer the questions that the project is trying to address. It involves identifying patterns and drawing out the main themes, and is often done with special computer software.

Arm
Refers to a group of participants assigned to a particular treatment. In a randomized controlled trial, assignment to different arms is determined by the randomization procedure. Many controlled trials have two arms: a group of participants assigned to an experimental intervention (sometimes called the treatment arm) and a group of participants assigned to a control (the control arm). Trials may have more than two arms.

Attrition
The loss of participants during the course of a study.

Audit
An audit of health care involves carrying out a systematic assessment of how well that care is being delivered. Current policy and practice is compared with an agreed standard, so that any problem areas can be identified and improved. Later, the audit can be carried out again to check that the changes made have actually made a difference.

Basic research
Basic research aims to improve knowledge and understanding, rather than finding a solution to a practical problem. It may involve work in a laboratory – for example to find a gene linked to a disease or to understand how

cancer cells grow. This kind of research can sometimes provide clues as to which avenues to explore to develop new treatments.

Bias
Bias in research is when the study outcome is influenced, intentionally or unintentionally. Bias may result from the research design, the influence of the researcher, or the influence of the study participants.

Blinding
The process of preventing those involved in a clinical trial from knowing which comparison group a participant belongs to. The risk of bias is minimized when fewer people know who is receiving the experimental intervention or the control intervention. Participants, caregivers, researchers, and analysts are all candidates for being blinded. Blinding of certain groups is not always possible, for example, surgeons in surgical trials

BP
Blood pressure

Caregiver
A caregiver is a relative, friend, or partner who provides (or intends to provide, or used to provide) a substantial amount of care to another person on a regular basis, but not necessarily through living with them.

Causal
If there is a causal relationship between two things, one thing is responsible for causing the other thing.

Clinical guideline
A systematically developed statement for practitioners and participants about appropriate health care for specific clinical circumstances. The clinical guideline may be developed from existing studies, expert consensus, or a combination.

Clinical research
Clinical research aims to find out the causes of human illness and how it can be treated or prevented. This type of research is based on examining and observing people with different conditions and sometimes comparing them with healthy people. It can also involve research on samples of blood or other tissues, or tests such as scans or X-rays. Clinical researchers will also sometimes analyze the information in patient records, or the data from health and lifestyle surveys.

Clinical trial
Clinical trials are research studies involving people who use health care services, which often compare a new or different type of treatment with "standard care" (commonly accepted best treatment). They test whether the new or different treatment is safe, effective, and any better than what already exists. No matter how promising a new treatment may appear during tests in a laboratory, it must go through clinical trials before its benefits and risks can really be known.

Cluster randomized trial
A trial where clusters of individuals (e.g. clinics, families, geographical areas), rather than individuals themselves, are randomized to different groups. Cluster randomized trials are common in research about health care because they are often easier to implement and more meaningful than other study designs.

Co-Sponsor
Where two or more organizations share a significant interest in a study, they may elect to act as co-sponsors.

Cohort study
An observational study in which a defined group of people (the cohort) is followed over time. The outcomes of people in subsets of this cohort are compared, to examine people who were exposed or not exposed (or exposed

at different levels) to a particular intervention or other factor of interest. A prospective cohort study assembles participants and follows them into the future. A retrospective (or historical) cohort study identifies subjects from past records and follows them from the time of those records to the present.

Collaboration
Collaboration involves active, on-going partnership with members of the public in the research process. For example, members of the public might take part in an advisory group for a research project, or collaborate with researchers to design, undertake, and/or disseminate the results of a research project.

Confidence interval
A measure of the uncertainty around the main finding of a statistical analysis. Wider intervals indicate lower precision and narrow intervals indicate greater precision.

Confidentiality
Protecting the identity of a research participant. During a research project, the researchers must put protective measures into place, to ensure that all of the information collected about the participants is kept confidential. This means that the researchers must get the participants' written permission to look at their medical or other records. It also means that any information that might identify the participants cannot be used or passed on to others, without first getting the participants' consent. For example, when researchers publish the results of a project, they are not allowed to include people's names.
This confidentiality will only be broken in extreme circumstances: where it is essential for the person's care, treatment or safety, where it is required by a court order, for example in a criminal investigation, or where it is necessary to protect the public.

Confounder
A factor that is associated with both an intervention and the outcome of interest that can change the apparent outcome of a study. For example, if people in the experimental group of a controlled trial are younger than those in the control group, it will be difficult to decide whether a lower risk of death in one group is due to the intervention or the difference in age. Age is then said to be a confounder, or a confounding variable. In experimental studies, randomization is used to minimize imbalances in confounding variables between experimental and control groups. Confounding is a major concern in non-randomized trials. In observational studies, confounding can be minimized by statistical analysis techniques.

Consultation
Consultation involves asking members of the public for their views about research, and then using those views to inform decision-making. This consultation can be about any aspect of the research process – from identifying topics for research, through to thinking about the implications of the research findings. Having a better understanding of people's views should lead to better decisions.

Consumer
The term consumer is used to refer collectively to:
• people who use services
• caregivers
• organizations representing consumers' interests
• members of the public who are the potential recipients of services
• groups asking for research to promote good health or because they believe they have been exposed to potentially harmful circumstances, products, or services.

Contamination
The unintended application of the intervention being evaluated to people in the control group; or unintended failure to apply the intervention to people assigned to the intervention group. For example, an experimental study that involves counseling by clinicians can be affected by contamination when clinicians inadvertently counsel patients in the control group, or fail to counsel those in the intervention group.

Control
A participant in the group that acts as a comparison for one or more experimental interventions. Controls may receive placebo, no treatment, standard treatment, or an active intervention, such as a standard drug.

Control Group / Arm
The groups being compared in the randomized trial. Also referred to as “study groups”, “treatment groups”, “the arms” of a trial, or by individual terms such as treatment and control groups.

Controlled Trial
A type of clinical trial in which observations made during the trial are compared to a standard (called the control). The control may be observations from a group of participants in the same trial or observations from outside the trial (for example, from an earlier trial, called a “historical control”).

Cost-effectiveness
A measure addressing the cost of achieving health benefits. To facilitate comparisons, health benefits can be quantified in several ways; one common measure is ‘QALYs’ (Quality-Adjusted Life Years), which incorporate both extra life achieved and improvements in quality of life. Knowing the cost associated with each QALY gained can help decision-makers assess whether the introduction of a treatment or service should be recommended.

Cost-effectiveness analysis
An economic analysis that describes the costs for some additional health gain (e.g. cost per additional stroke prevented).

CV
Curriculum Vitae – similar to a resume, but lists the scholarly products of the researcher, such as papers, grants, and presentations.

Data
Data are pieces of information collected through research. They can include written information, numbers, sounds, and pictures. Data are usually stored electronically, so that they can be analyzed, interpreted, and then communicated to others, for example in reports, graphs or diagrams. “Data” is plural. The singular is “datum”.

Dependent variable
A dependent variable is a variable whose value depends upon independent variables. The dependent variable is what is being measured in an experiment or evaluated in a mathematical equation. The dependent variable is sometimes called "the outcome variable."

Dissemination
Dissemination involves communicating the findings of a research project to a wide range of people who might find it useful. This can be done through:
• producing reports (often these are made available on the Internet)
• publishing articles in journals or newsletters
• issuing press releases
• giving talks at conferences.
It is also important to give feedback about the findings of research to research participants.

Double blind
A trial where neither the investigators nor the subjects included in the trial (healthy volunteers or patients) know which interventions / treatments have been assigned.

Effect size
A generic term for the estimate of treatment effect for a study.

Efficacy
The extent to which an intervention produces a beneficial result under ideal conditions. This is as compared with effectiveness, which is the extent to which an intervention produces beneficial results under more typical "real world" conditions.

Eligibility criteria
The key standards that people who want to participate in a clinical study must meet, or the characteristics that they must have. These include inclusion criteria and exclusion criteria. For example, a study might only accept participants who are above or below certain ages.

Engagement
Engagement in research refers to active involvement between people who use services, caregivers, and researchers, rather than the use of people as participants in research (or as research 'subjects'). Many people describe engagement as doing research with or by people who use services rather than to, about, or for them.

Enrollment
The act of admitting a participant into a trial. Participants should be enrolled only after study personnel have confirmed that all the eligibility criteria have been met and consent (if indicated) has been obtained. Formal enrollment must occur before randomized assignment in a randomized study.

Epidemiology
The study of population and community health, not just individuals.

Ethics
Ethics are a set of principles that guide researchers who are carrying out research with people. Ethical principles are designed to protect the safety, dignity, rights, and well-being of the people taking part. They include the requirement to ask each individual to give their informed consent to take part in a research project.

Evaluation
This involves assessing whether an intervention (for example a treatment, service, project, or program) is achieving its aims. A project can be evaluated as it goes along or at the end. An evaluation can measure how well the project is being carried out as well as its impact. The results of evaluations can help with decision-making and planning.

Evaluative research
Evaluative research seeks to assess or judge in some way, providing useful information about something, which cannot be gleaned by mere observation or investigation of relationships.

Evidence base
An evidence base is a collection of all the research data currently available about a health or social care topic, such as how well a treatment or a service works. This evidence is used by health care professionals to make decisions about the services that they provide and what care or treatment to offer people who use services.

Evidence synthesis
Evidence synthesis involves the development of techniques to combine multiple sources of quantitative and qualitative data to derive best evidence for use in healthcare.

Exclusion Criteria
Specific criteria that are defined within the study protocol that expressly exclude specific individuals from participating in a study, for example children in a study of adult conditions. The reasons for considering exclusion can range from safety issues, potential difficulties in management of particular participants, or the need to control variables within the study. Exclusion criteria must always be defended ethically to guard against discrimination.

Experimental research
This type of research allows researchers to explore cause and effect, and almost always involves new drugs, diagnostic tests, or other treatments. For example, experimental research would be used to see whether a new drug is effective in reducing blood pressure. The research design (in this example, most likely a randomized control trial) will tell the researcher whether any reduction in blood pressure is definitely due to the drug.

Factorial design
Factorial designs allow researchers to look at how multiple factors affect a dependent variable, both independently and together. Factorial design studies are named for the number of levels of the factors. A study with two factors that each have two levels, for example, is called a 2x2 factorial design. In a trial using a 2×2 factorial design, participants are allocated to one of four possible combinations. This type of study is usually carried out in circumstances where no interaction is likely.

Feasibility studies
Feasibility Studies are smaller studies that are done before a main study in order to answer the question "Can this study be done?" They are used to estimate important parameters that are needed to design the main study. They are often done in combination with acceptability studies, which answer the question "Will participants do this study?". For instance:

- willingness of participants to be randomized;
- willingness of clinicians to recruit participants;
- number of eligible patients, caregivers, or other appropriate participants
- characteristics of the proposed outcome measure and in some cases feasibility studies might involve designing a suitable outcome measure;
- Follow-up rates, response rates to questionnaires, adherence/compliance rates, etc.
- availability of data needed or the usefulness and limitations of a particular database
- time needed to collect and analyze data

Focus group
A focus group is a small group of people brought together to talk. The purpose is to listen and gather information. Focus groups (as opposed to individual interviews) take advantage of group dynamics and conversations between participants. It is a good way to find out how people feel or think about an issue, or to come up with possible solutions to problems.

Follow-up
A process of periodic contact with participants enrolled in the trial for the purpose of administering the assigned intervention(s), modifying the course of intervention(s), observing the effects of the intervention(s), or for data collection.

Funder
Organization providing funding for a study (through agreements, grants or donations to an authorized member of the employing and/ or health care organization). The main funder remains responsible for securing value for money.

Generalizability
The extension of research findings and conclusions from a study conducted on a sample population to the population at large. The larger the sample population, the more one can generalize the results.

Gold standard
The method, procedure, or measurement that is widely accepted as being the best available, against which new developments should be compared.

Grey literature
Grey literature is material that is less formal than an article in a peer review journal or a chapter in a book – it is not typically indexed and harder to find in a systematic search, so it's not easily tracked down. It includes internal reports, committee minutes, conference papers, web pages, factsheets, newsletters, and campaigning material. However, 'grey literature' may be made available on request and is increasingly available on the Internet.

Hypothesis
A *hypothesis* is an assumption, an idea that is proposed for the sake of argument so that it can be tested to see if it might be true. In the scientific method, the *hypothesis* is constructed before any applicable research has been done, apart from a basic background review.

Implementation
Implementation involves putting research findings into practice. This means using research findings to make appropriate decisions and changes to health care policy and practice.

Inclusion Criteria
Specific criteria which are defined within the study protocol that expressly include specific individuals to participate in a study e.g. individuals within a certain age range, with a specific condition, etc.

Informed Consent (IC)
A process by which a subject voluntarily confirms his or her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the subject's decision to participate. A person gives informed consent to take part only if his/her decision is given freely after that person is informed of the nature, significance, implications, and risks of the study. Informed consent is needed for all experimental studies including clinical trials, but also for many observational studies.

Interaction
An interaction effect happens when one explanatory variable interacts with another explanatory variable on a response variable. This is opposed to the "main effect" which is the action of a *single* independent variable on the dependent variable.
For example, let's say you were studying the effects of a diet drink and a diet pill (the explanatory variables) on weight loss. The "main effects" would be the effect of a diet drink on weight loss, and the effect of the diet pill on weight loss. The interaction effect happens when the drink and pill taken at the same time. It's possible the combination could speed up weight loss, or even slow it down.

Interim analysis
Analysis comparing intervention groups at any time before the formal completion of a trial, usually before recruitment is complete. Often used with stopping rules so that a trial can be stopped if participants are being put at risk unnecessarily. Timing and frequency of interim analyses should be specified in the protocol.

Intervention
An intervention is something that aims to make a change and is tested through research. For example, giving a drug, providing a counselling service, improving the environment, or giving people information and training are all described as interventions.

Intervention group
A group of participants in a study receiving a particular health care intervention.

Interview
In research, an interview is a conversation between a researcher and one or more people, where a researcher asks questions to obtain information from the person (or people) being interviewed.

Investigator
Researcher conducting the (clinical) study, those researchers leading the team are referred to as PI (Principal Investigator).

IRB (Institutional Review Board)
Institutional Review Board, often called "Human Subjects Committee". For organizations that conduct research, an IRB provides guidance and approval for research involving human subjects in order to comply with Federal laws relating to protection of the rights and safety of subjects. All research involving human subjects at an organization is subject to IRB review and approval.

Journal
A journal is a regular publication in which researchers formally report the results of their research to people who share a similar interest or experience. Each journal usually specializes in one particular topic area. The British Medical Journal (BMJ), Journal of the American Medical Association, Pediatrics, and The Lancet are examples of journals. Manuscripts are usually reviewed by others in the field before the editors decide to publish (see "peer review").

Lay (lay person)
The term 'lay' means non-professional. In research, it refers to the people who are neither academic researchers nor health care professionals. With the recent increase of patient and family engagement in the research process, lines between "professional" and "lay" participants are becoming increasingly blurred.

Lay (non-technical) summary
A lay summary is a brief summary of a research project or a research proposal that has been written for members of the public, rather than researchers or professionals. It should be written in non-technical language, avoid the use of jargon, and explain any technical terms that have to be included.

Mentor
A mentor is an experienced person willing to share their experience, knowledge, and wisdom to help, guide, and support someone who is less experienced. Mentors act as teachers, advisers, and may become friends. A person who is newly engaged in research can ask for a mentor to help them adjust to their new role.

Meta-analysis
A study that combines data and findings from multiple independent studies to draw conclusions about a research question. Well-done meta-analyses are often scientifically stronger than randomized controlled trials (RCTs).

Methodology
The term methodology describes how research is done. It will cover how information is collected and analyzed as well as why a particular method has been chosen.

Morbidity
Illness or harm.

Mortality
Death.

Multi-Site
A study conducted according to a single protocol but carried out at more than one site and by more than one investigator; one principal investigator oversees several local principal investigators.

Multisite trial/study
A trial conducted at several geographical sites. Trials are sometimes conducted among several collaborating institutions, rather than at a single institution – particularly when large numbers of participants are needed.

Null hypothesis
A null hypothesis is a type of hypothesis used in statistics that proposes that there is no difference in outcomes from an experimental condition or observational situation. For example, the null hypothesis in a drug trial would be that use of the drug does not change the outcome it is expected to change. For statistical reasons, data that prove the null hypothesis to be false are needed in order to prove that there is a beneficial effect of an intervention.

Observational study
A study in which the investigators do not seek to intervene, but simply observe the course of events. There is a greater risk of selection bias and confounding than in experimental studies. Observational studies are often less costly and quicker than experimental studies, and are frequently the first step leading to an experimental study.

Outcome
Research outcome is the end result of conducting research on a particular topic. It may be a list of statistics one ends up with after conducting a survey or it could be a conclusion, such as phonics is the best method for teaching reading based on research that collected pre- and post-1966 reading test results.

Outcome measures
Outcome measures are measurements of the effects of a treatment or service. They might include physical measurements – for example measuring blood pressure, or psychological measurements – for example measuring people's sense of well-being. So if someone takes part in research, they may be asked questions, or they may be asked to have extra tests to assess how well the treatment or service has worked.

Output
The final stage of research is disseminating the findings to an appropriate audience. Dissemination can take many forms: a paper in a journal, conference paper or presentation, a formal report, or a dissertation/thesis for postgraduate study, web-based materials, and many others.

Participant
A participant is someone who takes part in a research project. Sometimes research participants are referred to as research 'subjects'.

Participation
Taking part in a research study, for example people being recruited to take part in a clinical trial or another kind of research study, joining in a focus group, or completing a questionnaire.

Participatory research
This is a type of research where researchers and people who use services or caregivers are partners in a research project. The research addresses an issue of importance to service users or caregivers, who are engaged in the design and conduct of the research, and the way the findings are made available. The aim of the research is to improve people's lives. This isn't a research method – it's an approach to research, a philosophy.

Patient and public engagement
An active partnership between patients and/or the public and researchers in the research process, rather than the use of people as 'subjects' of research. Patient and public engagement in research is often defined as doing research 'with' or 'by' people who use services rather than 'to', 'about', or 'for' them. This would include, for example, engagement in the choice of research topics, assisting in the design, advising on the research project, or in carrying out the research.

Peer interviewing
Peer interviewing is where people are interviewed by others who have a similar experience to them – their peers. For example, in a project to find out about children's experiences of after school care, children with experience of

using after school care may act as peer interviewers, asking other children about their experience. Some researchers believe that this kind of interviewing enables people to talk more freely about their experience.

Peer review
A reviewing process by experts in the same area of study used for checking the quality and importance of reports of research. An article submitted for publication in a peer-reviewed journal is typically reviewed by at least three other experts in the area, and their approval is usually required for the article's acceptance for publication in that journal. Peer reviewers might be members of the public, researchers, or other professionals. Peer review helps to check the quality of a report or research proposal.
Members of the public who act as peer reviewers may choose to comment on:
• whether the research addresses an important and relevant question
• the methods used by researchers
• the quality of public engagement in the research.

Perspectives / user perspectives
A user perspective is often what people with experience of using health or social services are asked to bring when they get involved in research. They are asked to provide ideas, comments, and suggestions based on the unique insight they have from their knowledge and experience of life with a health condition. They cannot be representative of everyone who uses a particular service, but they can offer their own perspective, and often that of other people.

PI
Principal Investigator: The lead person at a single site designated as taking responsibility within the research team for the conduct of the study

Pilot studies
A pilot study, pilot project, pilot test, or pilot experiment is a small scale preliminary study conducted in order to evaluate feasibility, acceptability, time, cost, adverse events, and improve upon the study design prior to performance of a full-scale research project.

Placebo
A placebo is a fake or dummy treatment that is designed to be harmless and to have no effect. It allows researchers to test for the 'placebo effect'. The placebo effect is a psychological response where people feel better because they have received a treatment, and not because the treatment has a specific effect on their condition. By comparing people's responses to the placebo and to the treatment being tested, researchers can tell whether the treatment is having any real benefit.

Post Hoc Analysis
From Latin '*after this*', post hoc analysis consists of looking at the data after the experiment has concluded for patterns that were not specified when the study was initially designed.

Power
The probability of rejecting the null hypothesis when a specific alternative hypothesis is true. In clinical trials, power is the probability that a trial will detect, as statistically significant, an intervention effect of a specified size. Power is related to the number of participants in a study; the more participants, the higher the power. Ideally, we want a test to have high power, otherwise data that indicate a difference in outcomes may not be statistically significant, risking that a benefit of an intervention might be missed.

Pragmatic trial
A trial that aims to test a treatment in a 'real life' situation, when many people may not receive all of the treatment, and may use other treatments as well.

Preclinical study
Research using animals to find out if a drug, procedure, or treatment is likely to be useful. Preclinical studies take place before any testing in humans is done.

Primary outcome
The outcome of greatest importance.

Primary research (also called primary data studies)
Experimental or observational studies that generate new data. This is in contrast to secondary data studies, where existing data about people are investigated to draw conclusions.

Probability
The chance or risk of something happening. Probability is used very frequently in statistics, to determine if there is a true relationship between experimental or observational conditions and outcomes.

Protocol / research protocol
A protocol is the plan for a piece of research. It usually includes information about:
• what question the research is asking and its importance/relevance
• the background and context of the research, including what other research has been done before
• how many people will be involved
• who can take part
• the research method, including the data to be collected and any interventions
• what will happen to the results and how they will be publicized.
A protocol describes in great detail what the researchers will do during the research. Usually, it cannot be changed without going back to an IRB for approval.

Public health research
Public health is concerned with promoting good health, preventing disease, and protecting people from hazards, rather than treating illnesses. It covers topics like the control of infectious diseases, vaccinations, and helping people to adopt healthy lifestyles. It is more commonly observational (rather than experimental) research.
Public health research involves finding out new knowledge (or testing out existing ideas) to do with public health – so it might address questions about:
• the best ways to help people stop smoking
• how influenza spreads.

Qualitative research
Qualitative research is defined as studies that focus on why and how things happen and that do not use numerical data as their primary facts. Qualitative research is often done using interviews and focus groups, and is frequently the first step in gaining information about a new research topic. Qualitative research usually generates more questions than answers, and does not usually employ hypotheses or statistical analyses. An example of qualitative research is a project to determine why people want to stop smoking.

Quality Assurance (QA)
All those planned and systematic actions that are established to ensure that the trial is performed and the data is generated, documented (recorded), and reported in compliance with good clinical practice and any applicable regulatory requirement(s).

Quantitative research
In quantitative research, researchers collect data in the form of numbers. So they measure things or count things. Quantitative research might ask a question like how many people visit their doctor each year, or what proportion of children have had an MMR vaccine, or whether a new drug lowers blood pressure more than the drugs that are usually used. Quantitative researchers use methods like surveys, observational studies, and clinical trials.

Questionnaire
A questionnaire is a prepared set of written questions used to obtain information from research participants. Questionnaires can be completed on paper, using a computer, or with an interviewer.

Randomization
There are two components to randomization: the generation of a random sequence, and its implementation, ideally in a way so that those entering participants into a study are not aware of the sequence.

Randomized controlled trial (RCT)
A controlled trial compares two groups of people: an experimental group who receive the new treatment and a control group, who receive the usual treatment or a placebo. The control group allows the researchers to see whether the treatment they are testing is any more or less effective than the usual or standard treatment.
In a randomized controlled trial, the decision about which group a person joins is random (that is, based on chance). A computer will decide rather than the researcher or the participant. Randomization ensures that the two groups are as similar as possible, except for the treatment they receive. This is important because it means that the researcher can be sure that any differences between the groups are only due to the treatment.

Reporting/publication bias
The publication or non-publication of research findings, depending on the nature and direction of the results

Research methods or techniques
Research methods are a particular way of studying something in order to discover new information about it or understand it better. For example, a focus group is a research method that's typically used to understand a consumer's reaction to a product or service.

Research network
Research networks aim to bring together people who have an interest in research about a particular condition or group of people. Networks might be national or local. These networks encourage researchers to work together and improve the quality of research. For example, CYSHCNet supports research on health systems that impact children and youth with special health care needs and their families.

Research partner
The term research partner is used to describe people who get actively engaged in research, to the extent that they are seen by their 'professional' colleagues as a partner, rather than someone who might be consulted occasionally. Partnership suggests that researchers and service users/caregivers have a relationship that involves mutual respect and equality.

Retrospective study
A study in which the outcomes have occurred before the study commenced. Case-control studies and cohort studies can be retrospective, but randomized controlled trials never are. Secondary data studies are mostly retrospective studies, while primary data studies are usually prospective studies.

Reviewer
An individual with specific knowledge, experience, and skills in a field of practice who undertakes an independent review of a grant application or document for publication. The comments made by this independent 'external reviewer' are used to inform the funding decision or the preparation of a written document. See "Peer review" above.

Sample Size
The number of participants in the trial. Sample size measures the number of individual samples measured or observations used in a survey or experiment. For example, if you test 100 samples of soil for evidence of acid rain,

your sample size is 100. If an online survey returned 30,500 completed questionnaires, your sample size is 30,500. In statistics, **sample size is generally represented by the variable "n".**

Secondary outcome
An outcome used to evaluate additional effects of an intervention deemed as being less important than the primary outcomes.

Setting
The research setting is the environment in which research is carried out. This could be a laboratory or a 'real' setting, such as the subject's working environment if you are conducting research into people's working lives.

Source Documents
Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, subjects' diaries, pharmacy dispensing records, x-rays, etc.).

Statistically significant
A result that is unlikely to have happened by chance.

Statistics and statistical analysis
The practice or science of collecting and analyzing numerical data, especially for the purpose of making inferences from a representative sample. Statistical analysis uses a set of mathematical rules to analyze quantitative data. It can help researchers decide what data means. For example, statistical analysis can assess whether any difference seen between two groups of people (for example between the groups of people in a clinical trial) is likely to be a reliable finding or simply due to chance.

Sub-group analysis
An analysis in which the intervention effect is evaluated in a defined subset of the participants in a trial, or in complementary subsets, such as sex or age.

Subject
An individual who participates in a clinical trial as either a recipient of the investigational product or a control.

Treatment
The process of intervening with the aim of enhancing health or life expectancy. Sometimes, and particularly in statistical texts, the word is used to cover all comparison groups, including placebo and no treatment arms of a controlled trial and even interventions designed to prevent bad outcomes in healthy people, rather than cure ill people.

Treatment effect
An effect attributed to a treatment, which in a clinical trial is based on a comparison between active treatment and a placebo control or two or more treatment regimens.