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Research methods are the strategies, processes or techniques utilized in the collection of data or evidence for analysis in order to uncover new information or create better understanding of a topic.

There are different types of research methods which use different tools for data collection:

- Four main approaches
- Types of research

FOUR MAIN APPROACHES

They include:

- Quantitative Research
- Qualitative Research
- Pragmatic approach to research (mixed methods)
- Advocacy/participatory approach to research (emancipatory)

Quantitative research

Quantitative research is generally associated with the positivist/post positivist paradigm. It usually involves collecting and converting data into numerical form so that statistical calculations can be made and conclusions drawn.

Process: Researchers will have one or more hypotheses. These are the questions that they want to address which include predictions about possible relationships between the things they want to investigate (variables). In order to find answers to these questions, the researchers will also have various instruments and materials (e.g. paper or computer tests, observation check lists etc.) and a clearly defined plan of action. Data is collected by various means following a strict procedure and prepared for statistical analysis. Nowadays, this is carried out with the aid of sophisticated statistical computer packages. The analysis enables the researchers to determine to what extent there is a relationship between two or more variables.

This could be a simple association (e.g. people who exercise on a daily basis have lower blood pressure) or a causal relationship (e.g. daily exercise actually leads to lower blood pressure). Statistical analysis permits researchers to discover complex causal relationships and to determine to what extent one variable influences another. The results of statistical analyses are presented in journals in a standard way, the end result being a P value. For people who are not familiar with scientific research jargon, the discussion sections at the end of articles in peer reviewed journals usually describe the results of the study and explain the implications of the findings in straightforward terms.

Principles: Objectivity is very important in quantitative research. Consequently, researchers take great care to avoid their own presence, behavior or attitude affecting the results (e.g. by changing the situation being studied or causing participants to behave differently). They also critically examine their methods and conclusions for any possible bias. Researchers go to great lengths to ensure that they are really measuring what they claim to be measuring. For example, if the study is about whether background music has a positive impact on restlessness in residents in a nursing home, the researchers must be clear about what kind of music to include, the volume of the music, what they mean by restlessness, how to measure restlessness and what is considered a positive impact. This must all be considered, prepared and controlled in advance. External factors, which might affect the results, must also be controlled for. In the above example, it would be important to make sure that the introduction of the music was not accompanied by other changes (e.g. the person who brings the CD player chatting with the residents after the music session) as it might be the other factor which produces the results (i.e. the social contact and not the music). Some possible contributing factors cannot always be ruled out but should be acknowledged by the researchers. The main emphasis of quantitative research is on deductive reasoning which tends to move from the general to the specific. This is sometimes referred to as a top down approach. The validity of conclusions is shown to be dependent on one or more premises (prior statements, findings or conditions) being valid. Aristotle's famous example of deductive reasoning was: All men are mortal → Socrates is a man → Socrates is mortal. If the premises of an argument are inaccurate, then the argument is inaccurate. This type of reasoning is often also associated with the fictitious character Sherlock Holmes. However, most studies also include an element of inductive reasoning at some stage of the research (see section on qualitative research for more details). Researchers rarely have access to all the members of a particular group (e.g. all people with dementia, carers or healthcare professionals). However, they are usually interested in being able to make inferences from their study about these larger groups. For this reason, it is

important that the people involved in the study are a representative sample of the wider population/group. However, the extent to which generalizations are possible depends to a certain extent on the number of people involved in the study, how they were selected and whether they are representative of the wider group. For example, generalizations about psychiatrists should be based on a study involving psychiatrists and not one based on psychology students. In most cases, random samples are preferred (so that each potential participant has an equal chance of participating) but sometimes researchers might want to ensure that they include a certain number of people with specific characteristics and this would not be possible using random sampling methods. Generalizability of the results is not limited to groups of people but also to situations. It is presumed that the results of a laboratory experiment reflect the real life situation which the study seeks to clarify. When looking at results, the P value is important. P stands for probability. It measures the likelihood that a particular finding or observed difference is due to chance. The P value is between 0 and 1. The closer the result is to 0, the less likely it is that the observed difference is due to chance. The closer the result is to 1, the greater the likelihood that the finding is due to chance (random variation) and that there is no difference between the groups/variables.

Qualitative research

Qualitative research is the approach usually associated with the social constructivist paradigm which emphasizes the socially constructed nature of reality. It is about recording, analyzing and attempting to uncover the deeper meaning and significance of human behavior and experience, including contradictory beliefs, behaviors and emotions. Researchers are interested in gaining a rich and complex understanding of people's experience and not in obtaining information which can be generalized to other larger groups.

Process: The approach adopted by qualitative researchers tends to be inductive which means that they develop a theory or look for a pattern of meaning on the basis of the data that they have collected. This involves a move from the specific to the general and is sometimes called a bottom-up approach. However, most research projects also involve a certain degree of deductive reasoning (see section on quantitative research for more details). Qualitative researchers do not base their research on pre-determined hypotheses. Nevertheless, they clearly identify a problem or topic that they want to explore and may be guided by a theoretical lens - a kind of overarching theory which provides a framework for their investigation. The approach to data collection and analysis is methodical but allows for greater flexibility than in quantitative research. Data is collected in textual form on the

basis of observation and interaction with the participants e.g. through participant observation, in-depth interviews and focus groups. It is not converted into numerical form and is not statistically analyzed. Data collection may be carried out in several stages rather than once and for all. The researchers may even adapt the process mid-way, deciding to address additional issues or dropping questions which are not appropriate on the basis of what they learn during the process. In some cases, the researchers will interview or observe a set number of people. In other cases, the process of data collection and analysis may continue until the researchers find that no new issues are emerging.

Principles: Researchers will tend to use methods which give participants a certain degree of freedom and permit spontaneity rather than forcing them to select from a set of pre-determined responses (of which none might be appropriate or accurately describe the participant's thoughts, feelings, attitudes or behavior) and to try to create the right atmosphere to enable people to express themselves. This may mean adopting a less formal and less rigid approach than that used in quantitative research. It is believed that people are constantly trying to attribute meaning to their experience. Therefore, it would make no sense to limit the study to the researcher's view or understanding of the situation and expect to learn something new about the experience of the participants. Consequently, the methods used may be more open-ended, less narrow and more exploratory (particularly when very little is known about a particular subject). The researchers are free to go beyond the initial response that the participant gives and to ask why, how, in what way etc. In this way, subsequent questions can be tailored to the responses just given. Qualitative research often involves a smaller number of participants. This may be because the methods used such as in-depth interviews are time and labor intensive but also because a large number of people are not needed for the purposes of statistical analysis or to make generalizations from the results. The smaller number of people typically involved in qualitative research studies and the greater degree of flexibility does not make the study in any way "less scientific" than a typical quantitative study involving more subjects and carried out in a much more rigid manner. The objectives of the two types of research and their underlying philosophical assumptions are simply different. However, as discussed in the section on "philosophies guiding research", this does not mean that the two approaches cannot be used in the same study.

Pragmatic approach to research (mixed methods)

The pragmatic approach to science involves using the method which appears best suited to the research problem and not getting caught up in philosophical debates about which is the best approach. Pragmatic researchers therefore grant themselves the freedom to use any of the methods, techniques and procedures typically associated with quantitative or qualitative research. They recognize that every method has its limitations and that the different approaches can be complementary. They may also use different techniques at the same time or one after the other. For example, they might start with face-to-face interviews with several people or have a focus group and then use the findings to construct a questionnaire to measure attitudes in a large scale sample with the aim of carrying out statistical analysis.

Depending on which measures have been used, the data collected is analyzed in the appropriate manner. However, it is sometimes possible to transform qualitative data into quantitative data and vice versa although transforming quantitative data into qualitative data is not very common.

Being able to mix different approaches has the advantages of enabling triangulation. Triangulation is a common feature of mixed methods studies. It involves, for example:

- the use of a variety of data sources (data triangulation)
- the use of several different researchers (investigator triangulation)
- the use of multiple perspectives to interpret the results (theory triangulation)
- the use of multiple methods to study a research problem (methodological triangulation)

In some studies, qualitative and quantitative methods are used simultaneously. In others, first one approach is used and then the next, with the second part of the study perhaps expanding on the results of the first. For example, a qualitative study involving in-depth interviews or focus group discussions might serve to obtain information which will then be used to contribute towards the development of an experimental measure or attitude scale, the results of which will be analyzed statistically.

Advocacy/participatory approach to research (emancipatory)

To some degree, researchers adopting an advocacy/participatory approach feel that the approaches to research described so far do not respond to the needs or situation of people from marginalized or vulnerable groups. As they aim to bring about positive change in the lives of the research subjects, their approach is sometimes described as emancipatory. It is not a neutral stance. The researchers are likely to have a political agenda and to try to give the groups they are studying a voice. As they want their research to directly or indirectly result in some kind of reform, it is important that they involve the group being studied in the research, preferably at all stages, so as to avoid further marginalizing them.

The researchers may adopt a less neutral position than that which is usually required in scientific research. This might involve interacting informally or even living amongst the research participants (who are sometimes referred to as co-researchers in recognition that the study is not simply about them but also by them). The findings of the research might be reported in more personal terms, often using the precise words of the research participants. Whilst this type of research could be criticized for not being objective, it should be noted that for some groups of people or for certain situations, it is necessary as otherwise the thoughts, feelings or behavior of the various members of the group could not be accessed or fully understood.

Vulnerable groups are rarely in a position of power within society. For this reason, researchers are sometimes members of the group they are studying or have something in common with the members of the group.

Types of research

- Experiment
- Surveys
- Questionnaires
- Interviews
- Case studies
- Participant and non-participant observation
- Observation trials
- Studies using the Delphi method

Experiments: People who take part in research involving experiments might be asked to complete various tests to measure their cognitive abilities (e.g. word recall, attention, concentration, reasoning ability etc.) usually verbally, on paper or by computer. The results of different groups are then compared. Participants should not be anxious about performing well but simply do their best. The aim of these tests is not to judge people or measure so-called intelligence, but to look for links between performance and other factors. If computers are used, this has to be done in such a way that no previous knowledge of computers is necessary. So people should not be put off by this either. The study might include an intervention such as a training programme, some kind of social activity, the introduction of a change in the person's living environment (e.g. different lighting, background noise, different care routine) or different forms of interaction (e.g. linked to physical contact, conversation, eye contact, interaction time etc.). Often the interaction will be followed by some kind of test (as mentioned above), sometimes before and after the intervention. In other cases, the person may be asked to complete a questionnaire (e.g. about his/her feelings, level of satisfaction or general well-being). Some studies are just based on one group (within-group design). The researchers might be interested in observing people's reactions or behavior before and after a certain intervention (e.g. a training programme). However, in most cases, there are at least two groups (a between-subjects design). One of the groups serves as a control group and is not exposed to the intervention. This is quite similar to the procedure in clinical trials whereby one group does not receive the experimental drug. This enables researchers to compare the two groups and determine the impact of the intervention. Alternatively, the two groups might

differ in some important way (e.g. gender, severity of dementia, living at home or in residential care, etc.) and it is that difference that is of interest to the researchers.

Surveys: Surveys involve collecting information, usually from fairly large groups of people, by means of questionnaires but other techniques such as interviews or telephoning may also be used. There are different types of survey. The most straightforward type (the “one shot survey”) is administered to a sample of people at a set point in time. Another type is the “before and after survey” which people complete before a major event or experience and then again afterwards.

Questionnaires: Questionnaires are a good way to obtain information from a large number of people and/or people who may not have the time to attend an interview or take part in experiments. They enable people to take their time, think about it and come back to the questionnaire later. Participants can state their views or feelings privately without worrying about the possible reaction of the researcher. Unfortunately, some people may still be inclined to try to give socially acceptable answers. People should be encouraged to answer the questions as honestly as possible so as to avoid the researchers drawing false conclusions from their study. Questionnaires typically contain multiple choice questions, attitude scales, closed questions and open-ended questions. The drawback for researchers is that they usually have a fairly low response rate and people do not always answer all the questions and/or do not answer them correctly. Questionnaires can be administered in a number of different ways (e.g. sent by post or as email attachments, posted on Internet sites, handed out personally or administered to captive audience (such as people attending conferences)). Researchers may even decide to administer the questionnaire in person which has the advantage of including people who have difficulties reading and writing. In this case, the participant may feel that s/he is taking part in an interview rather than completing a questionnaire as the researcher will be noting down the responses on his/her behalf.

Interviews: Interviews are usually carried out in person i.e. face-to-face but can also be administered by telephone or using more advance computer technology such as Skype. Sometimes they are held in the interviewee’s home, sometimes at a more neutral place. It is important for interviewees to decide whether they are comfortable about inviting the researcher into their home and whether they have a room or area where they can speak freely without disturbing other members of the

household. The interviewer (which is not necessarily the researcher) could adopt a formal or informal approach, either letting the interviewee speak freely about a particular issue or asking specific pre-determined questions. This will have been decided in advance and depend on the approach used by the researchers. A semi-structured approach would enable the interviewee to speak relatively freely, at the same time allowing the researcher to ensure that certain issues were covered. When conducting the interview, the researcher might have a check list or a form to record answers. This might even take the form of a questionnaire. Taking notes can interfere with the flow of the conversation, particularly in less structured interviews. Also, it is difficult to pay attention to the non-verbal aspects of communication and to remember everything that was said and the way it was said. Consequently, it can be helpful for the researchers to have some kind of additional record of the interview such as an audio or video recording. They should of course obtain permission before recording an interview.

Case studies: Case studies usually involve the detailed study of a particular case (a person or small group). Various methods of data collection and analysis are used but this typically includes observation and interviews and may involve consulting other people and personal or public records. The researchers may be interested in a particular phenomenon (e.g. coping with a diagnosis or a move into residential care) and select one or more individuals in the respective situation on whom to base their case study/studies. Case studies have a very narrow focus which results in detailed descriptive data which is unique to the case(s) studied. Nevertheless, it can be useful in clinical settings and may even challenge existing theories and practices in other domains.

Participant and non-participant observation: Studies which involve observing people can be divided into two main categories, namely participant observation and non-participant observation. In participant observation studies, the researcher becomes (or is already) part of the group to be observed. This involves fitting in, gaining the trust of members of the group and at the same time remaining sufficiently detached as to be able to carry out the observation. The observations made might be based on what people do, the explanations they give for what they do, the roles they have, relationships amongst them and features of the situation in which they find themselves. The researcher should be open about what s/he is doing, give the participants in the study the chance see the results and comment on

them, and take their comments seriously. In non-participant observation studies, the researcher is not part of the group being studied. The researcher decides in advance precisely what kind of behavior is relevant to the study and can be realistically and ethically observed. The observation can be carried out in a few different ways. For example, it could be continuous over a set period of time (e.g. one hour) or regularly for shorter periods of time (for 60 seconds every so often) or on a random basis. Observation does not only include noting what happened or was said but also the fact that a specific behavior did not occur at the time of observation.

Observational trials: Observational trials study health issues in large groups of people but in natural settings. Longitudinal approaches examine the behavior of a group of people over a fairly lengthy period of time e.g. monitoring cognitive decline from mid to late life paying specific attention to diet and lifestyle factors. In some cases, the researchers might monitor people when they are middle-aged and then again after 15 years and so on. The aim of such studies is usually to determine whether there is a link between one factor and another (e.g. whether high alcohol consumption is correlated with dementia). The group of people involved in this kind of study is known as a cohort and they share a certain characteristic or experience within a defined period. Within the cohort, there may be subgroups (e.g. people who drink moderately, people who drink heavily, people who binge drink etc.) which allow for further comparisons to be made. In some cases, rather than following a group of people from a specific point in time onwards, the researchers take a retrospective approach, working backwards as it were. They might ask participants to tell them about their past behavior, diet or lifestyle (e.g. their alcohol consumption, how much exercise they did, whether they smoked etc.) They might also ask for permission to consult the participants' medical records (a chart review). This is not always a reliable method and may be problematic as some people may forget, exaggerate or idealize their behavior. For this reason, a prospective study is generally preferred if feasible although a retrospective pilot study preceding a prospective study may be helpful in focusing the study question and clarifying the hypothesis and feasibility of the latter.

Studies using the Delphi method: The Delphi method was developed in the United States in the 1950s and 1960s in the military domain. It has been considered particularly useful in helping researchers determine the range of opinions which

exist on a particular subject, in investigating issues of policy or clinical relevance and in trying to come to a consensus on controversial issues. The objectives can be roughly divided into those which aim to measure diversity and those which aim to reach consensus. Different ways to employ this method have been devised but they tend to share common features, namely a series of “rounds” in which the participants (known as “panelists”) generate ideas or identify salient issues, comment on a questionnaire (constructed on the basis of the results from the first round) and re-evaluate their original responses. After each round, a facilitator provides an anonymous summary of the forecasts/opinions made by the experts and of their reasons. There is no limit to the number of panelists involved but between 10 and 50 might be considered manageable. The panelists are chosen on the basis of their expertise which could take many forms (e.g. academic, professional or practical knowledge, personal experience of having a condition, being a service user etc.).

Techniques or tools used for gathering research data include:

Qualitative Techniques or Tools	Quantitative Techniques or Tools
Interviews: these can be structured, semi-structured or unstructured in-depth sessions with the researcher and a participant.	Surveys or questionnaires: which ask the same questions to large numbers of participants or use Likert scales which measure opinions as numerical data.
Focus groups: with several participants discussing a particular topic or a set of questions. Researchers can be facilitators or observers.	Observation: which can either involve counting the number of times a specific phenomenon occurs, or the coding of observational data in order to translate it into numbers.
Observations: On-site, in-context or role-play options.	Document screening: sourcing numerical data from financial reports or counting word occurrences.
Document analysis: Interrogation of correspondence (letters, diaries, emails etc) or reports.	Experiments: testing hypotheses in laboratories, testing cause and effect relationships, through field experiments, or via quasi- or natural experiments.
Oral history or life stories: Remembrances or memories of experiences told to the researcher.	

APPLICATIONS OF RESEARCH METHODS IN PHARMACOLOGY

Biomedical research is in general simply known as medical research. It is the basic research, applied research, or translational research. It is conducted to aid and support the development of knowledge in the field of medicine. An important kind of medical research is clinical research, which is distinguished by the involvement of patients. Other kinds of medical research include pre-clinical research, for example on animals, and basic medical research, for example in genetics.

- **Objectives and Hypotheses:** The primary research question in medical sciences should be driven by the hypothesis rather than the data. The research or clinical hypothesis is developed from the research question and then the main elements of the study — sampling strategy, intervention, comparison and outcome variables are summarized in a form that establishes the basis for testing, statistical and ultimately clinical significance. For example, in a research study comparing computer-assisted ace tabular component insertion versus freehand ace tabular component placement in patients in need of total hip arthroplasty, the experimental group would be computer-assisted insertion and the control/conventional group would be free-hand placement. The investigative team would first state a research hypothesis. This could be expressed as a single outcome (e.g., computer-assisted ace tabular component placement leads to improved functional outcome) or potentially as a complex/composite outcome; that is, more than one outcome (e.g., computer-assisted ace tabular component placement leads to both improved radiographic cup placement and improved functional outcome).
- **Research question:** How does low-intensity pulsed ultrasound (LIPUS) compare with a placebo device in managing the symptoms of skeletally mature patients with patellar tendinopathy? Research hypothesis: Pain levels are reduced in patients who receive daily activeLIPUS (treatment) for 12 weeks compared with individuals who receive inactiveLIPUS (placebo).
- **Objective:** To investigate the clinical efficacy of LIPUS in the management of patellar tendinopathy symptoms.
- **Testing of Hypothesis and Analytical Tools:** Paired T-test is used in profusion in medical sciences and pharmaceutical sciences. Readings are

taken for blood pressure, diabetes etc before administering a drug and after to help the researcher know whether the drug has been useful or not. In many cases where the dependent variable are not continuous in scale and are nominal in scale we can use Discriminant analysis or logistic regression. For example if we want to check if smoking and drinking alcohol causes heart attack or not.

For example, in a random sample of 30 hypertensive males, the observed mean body mass index (BMI) is 27.0 kg/m² and the standard deviation is 4.0. Also, suppose it is known that the mean BMI in non-hypertensive males is 25 kg/m². If the question is to know whether or not these 30 observations could have come from a population with a mean of 25 kg/m², to determine this, one sample t-test is used with the null hypothesis H₀: Mean = 25, against alternate hypothesis of H₁: Mean \neq 25. Since the standard deviation of the hypothesized population is not known, therefore, t-test would be appropriate; otherwise, Z-test would have been used.

t-test for two related samples: Two samples can be regarded as related in a pre- and post-design (self-pairing) or in two groups where the subjects have been matched on a third factor a known confounder (artificial pairing). In a pre- and post-design, each subject is used as his or her own control. For example, an investigator wants to assess effect of an intervention in reducing systolic blood pressure (SBP) in a pre- and postdesign. Here, for each patient, there would be two observations of SBP, that is, before and after. Here instead of individual observations, difference between pairs of observations would be of interest and the problem reduces to one-sample situation where the null hypothesis would be to test the mean difference in SBP equal to zero against the alternate hypothesis of mean SBP being not equal to zero. The underlying assumption for using paired t-test is that under the null hypothesis the population of difference is normally distributed and this can be judged using the sample values. Using the mean difference and other standard error of the mean difference, 95% confidence interval can be computed. The other situation of the two samples being related is the two group matched design. For example, in a case-control study to assess association between smoking and hypertension, both hypertensive and non-hypertensive are matched on some third factor, say obesity, in a pair-wise manner. Same approach of paired analysis would be used. For example, during retrospective analysis, patients are divided into groups according to severity of disease – mild, moderate

and severe form. Then results of clinical and laboratory analyses are studied in order to reveal variables which are statistically different in studied groups. Using these variables, Discriminant functions are built which help to objectively classify disease in a future patient into mild, moderate or severe form. In biology, similar principles are used in order to classify and define groups of different biological objects, for example, to define phage types of *Salmonella enteritidis* based on Fourier transform infrared spectra, to detect animal source of *Escherichia coli* studying its virulence factors etc.

REFERENCES

- <https://www.alzheimer-europe.org/Research/Understanding-dementia-research/Types-of-research/The-four-main-approaches>
- <https://libguides.newcastle.edu.au/researchmethods>
- <https://www.alzheimer-europe.org/Research/Understanding-dementia-research/Types-of-research/Research-methods>
- Prof. (Dr.) V P S Arora, Dr. N. Gangwar, Dr. A.Tandon; (2016)
Applications of research methodology: Chapter 13.