

Explanation of Evidence-Based Information

As the UK's leading charity in complementary cancer care, we aim to provide high quality, up to date, balanced information about complementary therapies both for those with cancer and for medical professionals. Our series of **evidence-based information sheets** look at a number of complementary therapies in detail, and include information about safety, history, research and use.

It is common to come across conflicting information and opinions about the benefits of complementary therapies. This sheet aims to explore why this is, to show why things are not as straight-forward as they may seem, and to help you to make well-informed decisions about complementary therapies.

What is evidence-informed medicine?

Our information sheets are "evidence-informed." This means we consider three things;

- **research evidence** – we thoroughly search huge electronic databases of research literature to find relevant studies. We then obtain and critically appraise the studies for quality before including them. The research information is summarised in the "What's the evidence?" section of our information sheets to give a clear unbiased picture of the research evidence.
- **clinical experience** – over years of practice, therapists gain experience and knowledge of what works and what does not. Our therapists see the effects of their work day in day out, and are constantly appraising and reflecting upon their work.
- **preference** – what therapies and treatments people with cancer choose for themselves. We hear from the people who use the Bristol Approach about the enormous benefits they experience.

What is research?

Research aims to tell us something we didn't already know about the real world. But there are many ways of describing something. For example you could describe a visit to a restaurant in words, or by giving it a rating out of ten. Words are descriptive, and give you a feel for what it was like to be there, whilst a rating gives an overall picture that is to the point, but doesn't give any detail. In the same way, different styles of research ask different questions about the same subject. Here are some examples:

Descriptive studies such as surveys are used to get an overall picture about a situation, for example, how often people suffer from a cold. You may have been asked to take part in a survey by telephone or on the street.

Qualitative studies ask people questions through interviews, focus groups or written questionnaires. They can help us to understand more about a situation. For example the researcher may want to know how people decide whether to take a day off work. This could not be expressed as a number!

Quantitative research puts things into numbers (or quantities) such as how many days were taken off work. These studies are designed to answer a specific question such as "Does taking pain killers reduce the length of time taken off work during a cold?" Questions such as "How well do you feel?" could also be answered on a scale of one to ten to give "wellness" a number. Rigorous statistical tests are used to see if the result is likely to have occurred by chance. Results that are not likely to have occurred by chance are known as being "statistically significant".

Quantitative research can be done on animals, or on humans. Drugs must go through long animal trials before they reach what is known as the “clinical trial”, where they are tested on a group of patients. The most trusted type of clinical trial is the **randomised controlled trial** (RCT), which is seen as the best way of getting bias-free results (see glossary for a description of “bias”). This is because:

- One group is given a drug or therapy, and another control group is not. The two groups are then compared. From this, the researcher can see whether the drug or therapy has had an effect. This is why the trials are called “controlled”.
- The participants and the researchers cannot choose which group participants go in. They are instead randomly allocated to one group or another. This is known as randomisation and prevents bias, such as a researcher putting all the most ill people into the group they think will give them the best chance of survival.

New drugs or therapies are usually tested on large numbers of people in several different trials. Sometimes different studies come up with different answers to the same question, which can be very confusing. **Systematic reviews** and **meta analyses** are types of studies that gather together all the evidence and weigh the positive and negative results to form an overall conclusion.

RCTs and complementary therapies

Researchers have encountered a number of problems with using RCTs to test complementary therapies. For example:

Study design It is difficult to keep it secret from the participants of a study as to whether they are in the treatment group or the “control” group when you are giving them a massage, teaching them meditation or using needles in acupuncture. This can result in a loss of “blinding” and possible “bias” (see glossary for definition) which can affect the results. Also, participants are randomly allocated (randomised) to the treatment or control group. This can be a problem for complementary therapies because the client needs to take an active part in the therapy by, for example, spending time meditating, listening to relaxation cds or practicing yoga. As a result, the therapy may come out badly in an RCT study.

What to test. When a new drug is tested, it first goes through small, early trials to decide what doses are appropriate and for how long it should be taken before being tested on a large scale. Complementary therapies often miss this level of testing because the dose has already been decided through trial and error, or because of lack of funding. Surprisingly, therapists are not always consulted about the trial design, and as a consequence trials sometimes use doses that are not big enough, too big or not given for the right length of time. This can lead to poor and misleading results.

Problems with funding. Research into complementary therapies is very poorly funded compared to drug research which has the backing of large pharmaceutical firms. As a result, studies are often small and short. When statistical tests are used to decide if the results are significant, small studies are only capable of revealing very large treatment effects, so important but small benefits may be missed. Complementary therapies are generally given over the course of weeks, months and years. Lack of funding makes it difficult to run a study for that long, which means that the therapy may not be given for long enough to be effective.

The placebo effect. It was noticed in the 1950’s that people felt better when given a pill with no active ingredient, otherwise known as a placebo. This non-specific “placebo effect” is often dismissed as irrelevant and of no benefit. However, some complementary practitioners see the placebo effect as a way of harnessing our own ability to heal and use it as an integral part (but not all) of their work. RCTs take the view that it is irrelevant and try to remove the effect through careful study design, so removing a potentially essential element of the complementary therapy being tested. This could lead to the therapy being delivered in a different way than is normal, and subsequently not working as well.

Complementary therapies treat whole people, not a single symptom. Each person may be treated with a different preparation or procedure according to factors such as emotional history or metabolic type. Often, RCTs test a drug by giving it to everyone with the same key symptom, so this important level of complexity is lost. As a result, the therapy may not work as well and come out badly in an RCT study.

How to put a number on a feeling. There are many questionnaires and scales that can be used to measure, for example, quality of life, depression or anxiety, but they do not always reflect the whole experience a person has, or may not work for certain types of people. RCTs are quantitative studies, and so may miss important information about how a person felt.

Systematic reviews and complementary therapies

Systematic reviews are generally very useful. However, there are some problems with trying to conduct systematic reviews of complementary therapies.

Variations in treatment. There are often different schools of thought within a single complementary therapy, and each practitioner may deliver the therapy slightly differently. Several RCTs may have been performed by different researchers, using a therapy with the same name that is very different to the therapy used in other studies. Frustratingly, this makes it impossible to compare results and come up with a **clear answer**.

Not enough good studies. Researchers may try to bring all the available evidence from RCTs together to make a conclusion about the effectiveness of a therapy. This technique is valid where there are lots of well-conducted, large trials. It is less valid and can lead to incorrect conclusions where studies are small or poorly conducted.

What is the best way to research complementary therapies?

These problems have come to light over time as the researchers do more work. Some argue that it is better to use qualitative techniques such as interviews, as this gives people the chance to express benefits that cannot be easily picked up by qualitative questionnaires and techniques. Others argue that these studies are too open to bias. However, with careful design, qualitative studies can provide valuable information about the benefits people experience.

There is now much debate over how best to test complementary therapies, and the research is improving all the time. For some therapies this is revealing exciting and positive evidence of their benefits. However, for many therapies there is still not enough good quality evidence for researchers to make a firm conclusion about their benefits. This is not to say that there are no benefits, or that they are clearly beneficial. It simply means that researchers have more work to do.

In an uncertain world.....

This exciting specialised area of research will continue to develop and challenge researchers to produce evidence of better quality that more accurately reflects the real world of complementary therapy practice. We fully expect that as research capacity and methodologies are developed it will be possible to reach clearer conclusions about the benefits of complementary therapies in the future.

In the meantime, Penny Brohn Cancer Care continues to offer therapies that demonstrate our commitment to an evidence-informed approach. We provide our evidence based information sheets to support twenty-five years of experience, the clinical excellence of our staff, and the feedback and preferences of people who have been to the centre. From our experience, we are confident about the benefits of our work and look forward to a time when all these types of evidence are drawn together for a truly integrated approach.

Glossary

What follows is a glossary of terms to help you read our information sheets as there are some terms used by medical researchers that you may not be familiar with.

Alternative medicine – please see **complementary and alternative medicine**

Anecdotal evidence – this is evidence, often passed by word of mouth, which has not been scientifically tested. It can come from passing observations, or from an individual case such as “My next door neighbour was cured when she...”. Anecdotal evidence can indicate that more research should be done.

Bias – In everyday language, someone who is biased has an opinion in a certain direction that makes them judge things in a certain way. In science, bias refers to anything within a study that can influence the results in a particular direction. This can include things as simple as a weighing scale that weighs too heavy (resulting in people getting a higher dose of the drug being tested), through to bias in the assumptions of the researcher when designing the study or interpreting the results.

Blind study, Blinding – People involved in a study including the participants and the researchers themselves should not know who is in the experimental group or who is in the control group. This is to stop their expectations (a type of bias) of whether the drug or therapy will work from affecting the results. It is difficult or even impossible to maintain blinding for therapies such as massage, aromatherapy or meditation.

CAM - please see **complementary and alternative medicine**

Case study – A case study looks in-depth at the treatment of one person, or a small group. These types of studies are good for sharing new techniques, or for identifying new diseases. As the number of people is small, it is difficult to tell if the results happened by chance and so the results cannot be relied upon.

Case-control study – A type of study which looks at what might have caused or prevented a disease, such as smoking, or eating more fruit. The histories of a group of people who have the disease (the “case” group) are compared to the histories of a group who do not have the disease (the “control” group).

Clinical Trial – Research studies that test a new drug or therapy using people. New medicines will have gone through rigorous safety checks before this stage. (**Randomised controlled trials** are a type of clinical trial, as are **cohort studies** and **case-control** studies.)

Cognitive – the functions of the brain to do with perception, memory, judgment, and reasoning, but not to do with emotions.

Cohort Study – a type of research study which compares one group of people to another group over a period of time. At the start of the study, a group of people are found who have an attribute such as a particular gene, or a particular diet. Another group of people who do not have that particular attribute, but are similar in other ways such as age, gender and lifestyle are also found. Both groups are followed over time, and their health monitored and compared to see if there are any differences. This can help identify things that cause or prevent disease.

Complementary and Alternative Medicine (CAM) Some CAM therapies are now widely used and accepted as beneficial additions to conventional medicine. These are known as complementary therapies. Those offered as a replacement for conventional medicine are known as alternative therapies,

Control group – the group of people in a research study who do not receive the treatment that is being tested. Results from the treatment group are compared to the control group to see if the treatment has had an effect.

Critical appraisal – Whilst there is widespread agreement on what makes a good study, not all research is done to a high standard. Critical appraisal is the process of judging a study against strict criteria to decide if it has been well designed to answer the question it sets, without the influence of bias or interference from other factors.

EBM – see evidence based medicine

Evidence based medicine (EBM) – This is how modern medicine decides which drugs or therapies to use. EBM takes into consideration the best available research evidence, the clinical experience of the practitioner and patient preference.

Randomised controlled trials and **systematic reviews/meta analyses** are often considered the best level of evidence to prove how effective a drug or therapy is.

Evidence Informed medicine (EIM) – a term used to better reflect therapeutic practices that do not have a firm research base to draw from. EIM includes all the elements of evidence based medicine by considering the best available evidence, clinical experience and patient preference.

Experimental group/Treatment group – see **Treatment group/experimental group**

Meta analysis/systematic review – see **systematic review/meta analysis**

Methodology, methodological – The design of a study, what is done and how. Some designs are better than others, or are better at answering certain types of questions. It includes things such as how the participants were “randomly assigned”, how many participants were included, how the therapy is administered and by whom and how the results were analysed.

Placebo/placebo effect – a placebo is an inactive drug or therapy given to participants of a research study as part of the control conditions to maintain blinding. In 1955 it was reported that 35% of people felt better when they were given a completely inactive drug or therapy (The Powerful Placebo by HK Beecher, 1955). <http://skepdic.com/placebo.html>. This was termed the placebo effect. Later studies vary, observing everything from 0-100% placebo effect. There are many theories about how the placebo effect works, from people trying to please their doctor by saying “yes I feel better”, giving an answer based on whether they think they have been given the active drug or therapy, through to theories about triggering natural healing responses, or the release of opioids. In some cases real physical improvements are observed, such as improved mobility. Some people argue that if it makes you feel better then it does not matter how it works, whilst others argue that to use the placebo effect knowingly is unethical.

Qualitative Study – not all things of interest can be expressed as a number! Qualitative studies represent experiences, feelings and what these mean to people. This is often in the form of rich descriptions and direct quotes from the participants. The researchers use

interviews, observation, or may even report their own direct experience. As well as reporting results that numbers cannot express, qualitative studies can be useful for generating new theories about how things work.

Quality of life – many studies into CAM therapies look at overall quality of life. This is usually assessed using a standard questionnaire that asks questions about such things as depression, self-esteem, life satisfaction and isolation.

Randomised Controlled Trial (RCT) – A type of scientific research study that tests how effective a drug or therapy is. “Randomised” means that the participants cannot choose which group they are in, and are instead randomly placed. “Controlled” means that one group is given a drug or therapy, and compared to another group (control group) that did not take the drug or therapy. From this, the researcher can see whether the therapy works. RCTs are considered to be the highest quality study as the special design reduces the chances of getting misleading results through bias (see definition below).

Randomization – participants in a study are randomly assigned to either the control group or the treatment group. Usually a computer or “table of numbers” is used. The aim of randomization is to get an even spread of types of people in each group, and to avoid bias such as the participant or researcher preferring one group over another.

Research study – an experiment.

Significant – see **statistical significance**

Statistical significance – usually expressed as P values or confidence intervals. Statistical significance is a mathematical way of deciding how likely it is that the results of a research study could have happened by chance. A one in twenty chance of the results having happened by chance is the acceptable level.

Statistics – mathematical tests performed on the results of a research study to help the researcher draw valid conclusions.

Systematic Review/meta analysis – Often several studies will look at the same question, and get a different answer. Systematic reviews attempt to make an overall conclusion by carefully finding all the relevant research studies relating to a particular question and looking at their results together. The studies that are used to make the overall conclusion are assessed for quality before being included. Where there are lots of studies that have been done in a similar way, a meta analysis can be performed, where all the individual results are pooled together and statistical tests run to give an overall figure. This number can be used to reach an overall conclusion about whether the new drug or therapy works.

Treatment group/experimental group – the group that received the treatment being given in a research study. The results from the treatment group are compared to the control group to see if the treatment has had an effect.

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