

NON-CONVENTIONAL treatment options in **BREAST CANCER**



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INTRO

The Anticancer Fund is a private Belgian foundation providing research-based information on standard and other treatments and the latest medicine via our website www.anticancerfund.org (contact: info@anticancerfund.org). We also inform patients as to which additional options may be available to them when standard treatment fails. This reliable cancer information is explained by our doctors and scientists in a language that is easy to understand. The Anticancerfund also selectively funds the development of promising therapies that are currently neglected and bringing the most valuable treatments to the patient as quickly as possible.

This guide was **created by a team of doctors and scientists** at the Anticancer Fund, to help breast cancer patients and their supporters make sense of the complex issue of non-conventional therapies for breast cancer. With this booklet, we want to help you deal with the volume of information that you may receive from family and friends, or find on the internet, the news, etc. It will help you to put non-conventional treatments into perspective regarding any statements made about these treatment options, and give you some guidance as to whether a treatment is trustworthy and potentially safe. We will also discuss scientific evidence in relation to some of the more popular non-conventional treatments for breast cancer.

In addition, we want to **make you aware of your rights and responsibilities** as a patient. We want to encourage you to take this information with you to your appointments with your doctor and/or oncologist, as a guide to discussing those topics which are of interest to you.

What is NON-CONVENTIONAL THERAPY?



A non-conventional treatment is a group of diverse medical and health care systems, practices and products that are not presently considered to be part of conventional medicine.

A treatment can be a drug, a food supplement or herbs, but also other things, such as acupuncture, mindfulness, yoga, etc. Another word often used instead of treatment is therapy. Non-conventional treatments are also known as non-mainstream treatment, Complementary and Alternative Medicine (CAM) or non-classical treatment. Although these terms are often used interchangeably, we will use the term non-conventional treatment throughout this booklet, for ease of reading.

Non-conventional treatments are those treatments that are not generally used in oncology practice and their effectiveness and safety is not always well-known. This is because these types of treatments – unlike conventional treatments – have not undergone extensive scientific testing. They are not part of what we call evidence-based medicine.

This also means that non-conventional treatments are mostly not reimbursed by health insurance – depending on the treatment and the country you live in.

Conventional treatment

As opposed to non-conventional treatment, conventional treatments are registered treatments that have been approved for a certain disease by the government. They have been thoroughly tested in the laboratory and in large clinical trials (see page 35), to find out if they are safe and whether they work.

This is a legal obligation when bringing a new treatment to the market. Other terms for conventional treatment are standard of care, (established) standard treatment, registered treatment, classical treatment and mainstream treatment.

Conventional therapies for breast cancer are chemotherapy, surgery, hormonal therapy, radiotherapy, biological therapies and immunotherapy. As conventional therapies are not the focus of this guide, we will not further elaborate on this topic.



Cures for breast cancer?

Currently, there are no non-conventional therapies with scientific evidence of curing breast cancer, but several have been proven to help manage symptoms and side effects of conventional treatment.

Some may even enhance the effect of certain conventional breast cancer treatments. The information in this booklet is meant to help you in your choice of whether or not to start a non-conventional treatment. Such a decision should always be made in close consultation with your doctor (treating physician) and/or oncologist.

Does this mean that none of the non-conventional treatments work, and that they are all unsafe?

No. It is just very difficult to distinguish between those that are safe and effective and those that are not. Hopefully, after reading this booklet, you will be a few steps closer to making that distinction.

A stack of seven books with various colored covers (white, orange, green, beige, red, yellow with white dots, red, yellow, and blue and white stripes) is shown on a light blue wooden surface against a solid blue background. The text is overlaid on the left side of the image.

What is
“PROOF”
for a specific
TREATMENT?

Scientific evidence

When we say there is proof for a specific therapy, we mean that extensive scientific research has been done on its efficacy (that is, does it work?). A very important part of this research is done in actual humans (through clinical trials).

By law, before a new drug for a certain disease or condition can be prescribed, it needs to be thoroughly tested in the test tube (*in vitro*), in animals (*in vivo*), and in humans, in order to prove that the treatment works and is safe.

For most non-conventional treatments no extensive research has been done. This also means there is no easy way to find out if the non-conventional therapy that you are interested in is safe or, moreover, will work.

Scientific evidence in the news

Quite often, a 'miracle cure', presented in a headline, turns out to have been tested only on cells in the test tube or in animals. Isn't this enough? No, and this is why: Whilst research in cells and in animals is essential when developing a new treatment, it represents only the early stages of research. To really know whether a treatment will work in patients, research is needed in human beings.

Why is it so important to do research with patients?

Many drugs that show promising results in the test tube do not go on to work in animals, and many drugs that show promising results in animals do not work in humans. The body is a complex system with many aspects to consider. A tumour does not act independently from the rest of the body. Many factors may influence the way a tumour reacts to a drug – factors that cannot be taken into account when doing tests outside the human body.

The placebo effect

Many patients actually feel better when they believe they are being treated with something that is meant to make them feel better, even when the treatment is doing nothing at the biochemical level.

Merely by believing the treatment will work, patients can experience effects as if it were. This is called the placebo effect. However, there is a big difference between a treatment having a physical effect on your cancer (such as destroying cancer cells) and it simply making you feel better, without affecting the cancer itself.

This said, the placebo effect has demonstrated proven benefits for quality of life, and its powerful effect is currently being studied in neuroscience research. It has been shown that in non-conventional treatments many of the positive effects experienced by patients are due to the placebo effect. ■

Various elements add to experiencing a placebo effect:

- › The attention a patient receives from a practitioner and his/her team
- › The fact that the patient and his/her supporters are convinced by the treatment and the hope that comes with it
- › The surroundings in which the treatment is given
- › The relationship with a practitioner: The bigger the trust in a practitioner, the stronger the placebo effect will be.



How do I know if the treatment of my choice is safe?

Next to knowing if a treatment works, it is extremely important to know if it is safe. Before bringing a new (conventional) treatment to the market, extensive scientific research will have been done – not only on its efficacy (effectiveness), but also on its side effects. As with assessing efficacy, assessing safety of a treatment is done through clinical trials.

Even treatments that you may believe to be harmless because of their apparent 'innocent' nature – for example dietary supplements or herbs – may be harmful. They may, for example, interfere with your conventional treatment or make the side effects from the conventional treatment worse. For this reason it is of the uttermost importance that you discuss any non-conventional treatment with your doctor before taking it.

One example of a seemingly harmless supplement is **vitamin B17** – or **Laetrile** – found in various seeds and plants, such as apricot kernels. Breakdown of Laetrile results in large amounts of cyanide (a highly poisonous substance) which, it is claimed, has anticancer effects. However, scientific research has shown it is not only ineffective as a treatment of any cancer, but also potentially dangerous.

Laetrile can cause cyanide poisoning and liver problems, if taken in high doses. Side effects can include nausea, vomiting, headache, dizziness, liver damage, low blood pressure, walking difficulties, fever, coma and even death, amongst others.

More information about Laetrile is available on the ACF-website (<http://www.anticancerfund.org/therapies/laetrile>)

Another significant example, in relation to safety issues of non-conventional treatments, is **shark cartilage**.

Shark cartilage became popular in the early 2000s after widely broadcasted anecdotal case histories, accompanied by claims that sharks are not affected by cancer. Shark cartilage is still a popular alternative treatment for cancer, despite the general lack of efficacy reported in research papers.

Cartilage is a tissue, in addition to bone, found in the skeleton of humans and animals. Sharks' skeletons are made purely of cartilage. It is claimed that shark cartilage prevents the formation of new blood vessels in tumours (which a tumour needs for growth and spread of cancer cells). However, no studies have shown that shark

cartilage is actually helpful in the treatment of cancer. One recent study, in patients with advanced breast or colon cancer, showed no benefits of shark cartilage regarding cancer growth or quality of life.

Unfortunately, taking shark cartilage pills can cause side effects such as sickness, vomiting, belly pain, bloating and constipation, as well as dizziness, low blood pressure, tiredness, and weakness, amongst others. Shark cartilage can also be harmful to the liver. More information about Shark Cartilage is available on the ACF-website (<http://www.anticancerfund.org/therapies/shark-cartilage>)

Shark cartilage and Laetrile are sold as dietary supplements, meaning there is little control over their quality and safety. ■



False claims in cancer treatment

*'Cannabis oil is the cure for cancer.'
'You should cut out all sugar/fat/
carbohydrates from your diet.'
'Soy will kill all breast cancer cells.'*

The list of supposed cures for breast cancer is getting longer. When diagnosed with cancer, it is only natural that you might wish to start looking for alternative treatment options and radical solutions, which can open up a world of claims for so-called 'miracle cures'. In this chapter, we aim to help you assess the trustworthiness of pronounced non-conventional 'cures' for breast cancer.

Source

When trying to assess whether information is trustworthy, the first thing to do is look at the source of the information: Who wrote or said it? This is always an important question to ask, whether you read about it in a headline in the newspaper, on the internet or someone simply told you about it.

› *Was it the company selling the treatment? They stand to gain from making you believe their treatment is worth your money – so keep a critical eye.*

› *Was the source a medical doctor? Be sure to check his/her credentials before believing everything he or she says.*

Internet

On the internet you can easily access all sorts of information on a wide variety of health issues, including breast cancer, but there are no regulations as to what can be posted on a website: **anyone can post anything**. It is difficult to know whether the

“ If a website has a HONcode certification, it means that the medical and health information published on the website is reliable and trustworthy. ”



information you are reading on the net is trustworthy and complete. Therefore you should always ask yourself the following questions:

› *What is the purpose of the website? Is it for marketing or selling of a product, or to provide information?*

› *Who creates the content of the website? Is it a reliable source, such as a university or the government?*

› *Does the website contain a HON code?*

› *Has it been recently updated?*

› *Is there evidence, in the form of published research, to support the claims listed on the website?*

› *Does the website only mention positive results and nothing about side effects?*

› *Are there a lot of testimonials from 'cured'- patients? Please consider the possibility that these could be made up by the seller of the treatment.*

Books

Information may become outdated very quickly; new research results are reported every day. If the book you are reading is not very recent, it is likely that you are not getting the most up to date information.

You should also remember that a book written by a single author only provides you with the view of that author. You should ask yourself:

› *Was the book recently published? (For example within the last couple of years)*

› *Does the author have good credentials? Is he/she, for example, a researcher at a university?*

› *Has the book been reviewed by other experts? (i.e. peer reviewed)*

› *Is the information in the book based on scientific research, including research on humans?*

Word of mouth and testimonials

Very often you will find testimonials of patients who were treated with the therapy being sold. When

reading testimonials, keep in mind that, generally, patients who believe they were helped, or even cured by a non-conventional treatment, are keen on sharing their story with the people around them.

Testimonials, whether on the internet or passed by word of mouth, are given with a desire to help others. As human beings, we have a tendency to believe and generalize things that are based on a single personal experience.

However, it is not possible to properly evaluate a treatment based on the experience of only one patient. When someone tells you about a revolutionary new treatment, and strongly encourages you to try it out, ask yourself the following questions:

› *Who is this particular person? What are his or her beliefs?*

› *Where did the person get the information?*

› *Is there scientific evidence to back up what they are saying? Have any large clinical trials been carried out to support this patient's findings?*

Scientific publications

Scientific publications are a good source of information about a treatment. Unfortunately, research articles are written in such a way that it can be difficult for lay persons to understand. However,

individuals with a scientific background, as well as specific organisations, can help patients by interpreting the scientific information.

You can also contact us (info@anticancerfund.org) for more information about scientific publications. ■



Red flags

To summarise, there are some general red flags when it comes to searching for and evaluating trustworthiness of non-conventional treatments for breast cancer:

› **Be aware it is not possible to generalise the effect of a treatment from one person to the whole breast cancer population.**

To be able to make a statement for all breast cancer patients – or even a sub-group – rigorous testing, in clinical trials involving large numbers of patients, is necessary. In addition, it is important to realise that – due to the unique nature of each human being and each tumour – something that helps one patient, may not help another.

› **Do not believe everything you read.** Anyone can put anything on the internet, without the content being supervised or controlled in any way.

› **Do not be influenced by shiny websites with lots of testimonies and promising claims.** If it sounds too good to be true, it probably is.

› **Do not let fear or desperation cloud your judgment,** however hard this may be in the given circumstances.

› **Be extra vigilant when it comes to private clinics,** as they make their money by appealing to patients that are desperately looking for options. Does this mean that every private clinic has bad intentions and is lying? No. But be sure you check it out thoroughly before spending your money on expensive treatments, often abroad.

› **If a website or book claims a therapy is a 'miracle', 'secret cure' or that it treats any cancer, be very cautious. No such treatments have been discovered so far.**

Quacks and how they work

By quackery we mean the promotion of fake medical practices. A quack or fraud is a person who pretends, professionally or publicly, to have skill, knowledge or qualifications he/she does not possess. Many people believe that quackery or fraud is easy to spot but, very often, it is not. In this chapter we discuss some of the strategies used by quacks, which explain their success in the field of cancer treatments.

The word fraud or quack conjures up notions of dodgy, foreign characters selling suspicious potions in a dark alley or out of the trunk of a car. Naturally, any intelligent human being believes they would never fall into that trap. Unfortunately, most successful quacks are not so easy to expose.

Modern quack doctors are extremely skilled salesmen, who know exactly what to say to convince patients to try out their treatments. They will hide themselves and their declared cancer cures behind scientific terms and (mis)quotes from scientific publications. They may come across as intelligent and educated persons, and attempt to evidence this by presenting you with an impressive CV. However, what is being sold is not the quality and effectiveness of the treatments put forth, but rather his/her ability to influence others, to tell patients exactly what they wish to hear and to reach patients on an emotional level.

Tricks used by fake doctors

A strategy that is often used by quacks to convince their audience is that of shifting the blame.

Effectively, blame is shifted depending on the outcome: if the treatment doesn't work as promised, it is deemed to be because earlier standard treatments – such as chemotherapy and radiation – have demolished the body's own healing system, immune system or, in some other way, have pre-



vented the fake treatment from working. Another reason often stated is that the treatment was not given a chance to work properly because the patient started it too late. Whatever the reason, the aim is to blame the patient if the treatment does not work as promised. This excuse may also be used if the patient realises the fake nature of the treatment and, consequently, decides to abandon it.

What are we measuring?

Another trick that fake doctors will employ is to use 'alternative endpoints' (which are extremely difficult to verify or measure) as opposed to using objective, meas-

urable endpoints (outcomes). An endpoint is what researchers look at in a clinical study, in order to see if a treatment works. It means that something will have changed if the treatment has been effective.

In clinical trials, endpoints are often one of the following: the visible decrease of the tumour on a scan, the number of people whose cancer goes away or the percentage of survivors. In other words, an endpoint is something that is measurable and directly related to the tumour.

Quacks, however, will claim vague outcomes for their treatments, such as 'the restoration of your body's natural defense mechanisms', 'detoxification' of your body or 'cleansing' of your system. These types of endpoint are difficult or impossible to truly measure, making it hard to evaluate the treatment provided.

I feel cared about

As human beings, we are susceptible to other things than the purely physical. Consequently, quacks may use various strategies to engage you on an emotional and psychological level and make you feel you are being cared about.

For example, they may write down your private thoughts and concerns (the ages and names of your children, your worries and fears, your husband's profession), in order to be able to bring them up during future appointments. The aim is to make you feel as if genuine interest is being taken in you as a person. ■

Some false claims highlighted

Below, we highlight some of the known fraudsters and their treatments.

German new medicine

German new medicine was invented by a German doctor called Dr. Hamer. It is practised by a group of believers who claim that cancer, including breast cancer, is simply the result of an emotional shock – for example, the loss of a loved one or being laid off at work. According to German new medicine, milk duct cancer is a result of a separation conflict (from a child, spouse or other partner). "...a right handed woman will respond with the left breast if she has a mother-child conflict or a daughter-mother conflict and will respond with the right breast if she has a partner conflict ... The opposite breast will be affected in a left handed woman..."

Believers claim that when the 'shock' is resolved, the body will return to normal and the cancer will disappear. It may not be surprising that Dr. Hamer and his followers have not been able to show scientific evidence for this theory. Meanwhile, Dr. Hamer's medical license has been withdrawn, and he has spent almost 2 years in prison. His 'therapy', however, continues to be administered to patients by other doctors. On his website, instead of scientific evidence, testimonials are published.

Whether these testimonials are written by real patients or simply invented can only be guessed at. Causing cancer patients to abandon (or not even start) treatment of their cancer is the most dangerous form of quackery. German new medicine advocates this by convincing patients that their cancer will disappear by itself (and with

help from "only the absolutely necessary intervention" (although it isn't quite clear from the website what is meant by this).

GcMAF

GcMAF is a protein that is claimed to cure cancer, autism, Alzheimer's and a number of other diseases. The catchphrase used on the website of Immuno Biotech Ltd. (the company selling the product) is "GcMAF is the body's own internal medicine. ALL healthy people have it." None of the claims for the effectiveness of this product has a solid scientific basis.

One researcher – Nobuto Yamamoto – and his group, refers to three clinical studies as evidence that GcMAF can cure cancer. However, a detailed review of these trials, involving discussions with experts, has identified serious faults in this research – both in the methods employed and the endpoints used to draw conclusions.

Immuno Biotech Ltd. is currently under investigation by European regulatory authorities. The factory where GcMAF was being manufactured in the UK has been closed down because of concerns about the purity of the product and the equipment used to produce it. Not only have UK authorities shut down the factory but, in order to protect patients, it is no longer allowed to even import GcMAF.

Immuno Biotech Ltd. opened three treatment centres, including one in Switzerland, which was closed down by Swiss authorities in 2015. For more information on GcMAF, please visit <http://www.anticancerfund.org/therapies/gcmaf>

Conspiracy Theories

An idea that is extremely popular on social media and the internet in general is that a cure for cancer has already been discovered, but is being covered up. It is claimed that the medical establishment (the government, pharmaceutical companies etc.) conspires against 'natural' cures for cancer, by preventing the proof of these from being revealed, in order to make money from selling standard treatments, such as chemotherapy.

Thus a common claim made by quacks is that 'the war on cancer' is a lie. Often, the headline of their investigations is some version of 'What They Don't Want You to Know'. Why? Because 'cancer is a billion dollar industry', and treatment x or y (being some kind of natural, cheap treatment) cures cancer so effectively that if it came out it would bring down this industry. Many of the arguments used by the advocates of this theory are unscientific and abuse the fact that the larger part of the world's population cannot assess their accuracy.

However, if we consider what the world would have to look like for this conspiracy theory to be true (for example, the deliberate intention by thousands of people to cause widespread harm for monetary gains) we can begin seeing flaws in the reasoning behind it. ■





COMPLEMENTARY
Alternative therapies



The phrases *complementary therapy* and *alternative therapy* are often used as if they were the same thing. This is a mistake: there is a tremendous difference between the two.

A complementary therapy is a therapy that is used alongside your conventional treatment or therapy, and does not replace any conventional treatment that you are receiving. Complementary treatments may help you feel better and cope better with cancer and any side effects of standard treatment. In some cases, it may improve the effectiveness of your conventional treatment.

It is important to discuss, with your doctor or oncologist, any complementary treatments that you are considering. Why? Because not all complementary treatments will necessarily be beneficial to you. Some complementary therapies could stop conventional treatments working as well as they should. Others could be harmful to your body. The safety of any complementary therapy will depend on its type, and on the conventional treatment you are receiving.

An alternative therapy is meant to be used instead of conventional treatment. As mentioned before, all conventional cancer treatments have to go through rigorous scientific testing by law to prove that they work. Most alternative therapies have not been tested in this way. Consequently, there is no scientific evidence that they work. In addition, some alternative therapies could cause harm to your body instead of helping you.

Alternative treatments

Alternative therapy is something that is used instead of conventional medical treatment. The danger of alternative treatments is that they make you abandon your established treatment for a treatment of which there is no proof that it works. The situation is different if you have run out of conventional treatment options for your breast cancer. Many patients are not ready to accept that there is nothing more they can do, and consequently turn to alternative treatment options. You will understand this is a completely different situation from quitting existing scientifically-based cancer treatment to start an alternative treatment instead.

Despite widespread claims, there is no scientific evidence to support the use of any non-conventional treatment as a replacement for conventional cancer care. As studies in breast cancer show, delaying treatment or substituting alternative treatment for conventional treatment dramatically worsens outcomes. For this reason we will not go into the specificities of alternative treatments for breast cancer.

How do I look for a complementary therapy?

If you wish to discover whether there is complementary therapy that could be of benefit to you, it is advisable to talk to your doctor or oncologist.

Some questions you may wish to ask are:

› Are there any appropriate complementary therapies for my type of breast cancer, for my symptoms?

› Are there complementary therapies for the side effects I am experiencing from my treatment?

› Are any of these therapies offered in this hospital?

› What are the likely side effects of these complementary therapies, if any?



On the ACF website (www.anticancerfund.org) you can find reliable and trustworthy information about complementary therapies. You can also contact us (info@anticancerfund.org) ■

Before starting a complementary treatment therapy

Again, before starting a complementary treatment, it is extremely important to discuss it with your doctor and/or oncologist. This is true at any stage of your disease, but even more so if you are already in the middle of breast cancer treatment.

Many patients do not tell their doctors when they are using or thinking of using non-conventional treatments. Sometimes they are worried that the doctor will not agree and will tell them to stop, while at other times they may think it is not classed as a treatment or is simply not important enough to mention.

Why is it important that you tell your doctor?

Some non-conventional therapies, when taken together with your conventional treatment, could interact with the conventional treatment. Consequently, the effectiveness of the conventional treatment could be reduced, or the side effects increased. This could even be the case

for substances you may think of as 'harmless', such as food supplements, vitamins or herbs. Although supplements are considered safe by many patients because they are 'natural', they can actually be potentially harmful as a result of drug interactions, toxicities, and con-

tamination. In addition, authorities do not require manufacturers to produce any data regarding scientific background, effectiveness or safety of their products before bringing them to the market, meaning these products can be a big health risk. ■



Finding a practitioner

It is essential for your safety and wellbeing that any practitioner you find, to administer your non-conventional treatment or therapy, has been through the required training and possesses appropriate qualifications.

Choosing a practitioner should be done with the same care as selecting a doctor or oncologist. Finding such a practitioner can be challenging, depending on which therapy you are interested in. When you have identified a practitioner, it is useful to talk to him/her before making any decisions.

Before deciding on the treatment, questions you should ask your practitioner are:

› *What training/qualification does he/she have?*

› *Does he/she have any cancer-specific training, apart from training for the therapy?*

› *What benefits might you be expected to experience from the therapy?*

› *How long did the practitioner train for, and how long has he/she been practising?*

› *How frequently does the practitioner treat patients with problems similar to yours? What are the results?*

› *What does the treatment cost, and how long will it take? Is it fully or partly covered by public or private health insurance?*



Depending on which country you live in, it may or may not be obligatory for practitioners to register themselves.

If it is, this places them more or less under supervision of the government. If it is not, this poses an extra challenge in finding out whether they are respectable. ■

Stopping a therapy

Please be assured that you can stop any therapy (conventional or non-conventional) at any time, without having to give a reason.

You should always discuss this with your doctor/oncologist, but you are under no obligations to anyone when it comes to your own treat-

ment choices; they are personal, and you do not need to justify your choices to anyone. ■



A photograph of a person practicing yoga on a beach at sunset. The person is in a seated position, performing a yoga pose with their hands in a mudra. The background shows the ocean and a bright, golden sunset sky. The overall mood is peaceful and serene.

COMPLEMENTARY TREATMENTS FOR BREASTCANCER

In this chapter, different types of complementary treatments will be discussed. The therapies are divided into five main subtypes: Mind-body interventions, diets and nutrition, natural products, manipulative and body-based therapies and physical activity.

We will also give information about some of the most popular complementary treatments for

breast cancer, their scientific proof and safety. By popular, we mean that these treatments are often named in the news and are found all over the internet. Be aware that, just because we discuss a treatment here, it does not automatically mean this is a treatment you should start.

Please read carefully what the scientific evidence is, for each one

of the treatments discussed. The list of treatments examined is, of course, far from complete: the selection is based on the general popularity of a treatment. It is therefore quite likely that you will not find a specific treatment you have heard about.

If this is the case, please have a look at the Therapies tab on www.anticancerfund.org. ■

Mind-body interventions

The term mind-body interventions, refers to all treatments or techniques that are focused on interactions between the mind and body. They are based on observations that your mind is able to affect your body.

The communication paths between the body and the mind are complex. Many factors and systems influence our inner balance (the environment, our brain, our hormones, our immune system etc.). Within us, there is a huge communications network between these systems. The study of the interaction between psychological processes and the nervous and immune systems of the human body is called psychoneuroimmunology (PNI). There is extensive, ongoing research in neurosciences on this topic, and there are interesting results emerging that hopefully will be validated in patients.

Wellbeing

It is important to realise that using these networks in your body, you can actively engage in your healing process.

Dealing with stress

Being diagnosed with cancer causes stress, and each individual deals with it in a different way. Learning how to cope with long-lasting stress is very important, not only for you as a patient, but also for your daily caregivers, such as family members and close friends. Breast cancer treatment may also be a direct cause of stress. Finding a way to be calmer may substantially enhance your general wellbeing. Furthermore, it has been shown that stress has a negative impact on the immune system, so decreasing stress will have a positive effect on the immune system. There are a variety of treatments that are claimed to stimulate the immune system through different mind-body approaches.

Choosing a mind-body intervention

It is important to realise that mind-body techniques are not protected disciplines in most European countries. This means there is no control over who may practise these mind-body interventions, as is the case for many non-conventional treatments. You should therefore be very cautious when searching for a practitioner.

Popular Mind-Body therapies – Yoga

What is it?

Yoga is a practice originating in India over 5000 years ago, and is now very popular in Western countries. Yoga usually consists of physical exercises, such as stretches (or asanas), breathing techniques and meditation or relaxation. The meaning of the word yoga is to join, indicating the joining of mind and body. There are several different styles of yoga including Hatha yoga, Bikram yoga and Ashtanga yoga. Some are quite active, while others are gentler and focus more on meditation and breathing exercises.

Is it safe?

Yoga is generally safe when practised appropriately. It is among the most commonly used complementary therapies for breast cancer-related side effects and symptoms.

Does it work?

There is no scientific proof that yoga can cure any type of cancer. Research in breast cancer patients does show some evidence of a short-term, positive effect on general well-being. Yoga may also help

“All treatments that are focused on the interactions between the mind and body.”

in reducing breast cancer-related tiredness (fatigue). Whether yoga can help with pain, sleep and psychological health (distress, anxiety, depression) in breast cancer patients, has not been confirmed or denied, although many studies have reported positive effects.

The current evidence shows that yoga practice could help patients recovering from breast cancer, in enhancing health and managing some treatment-related side effects. The conclusion is that bigger and well-constructed studies are needed to make definite statements about the effects of yoga, but the evidence available at this moment points to an overall positive effect of yoga on breast cancer patients. ■

Mindfulness

What is it?

The term mindfulness refers to a relaxed state of awareness of both our inner world (thoughts, feelings and sensations) and the constantly changing outer world, without trying to control anything. It involves being here in the moment, without striving or judging. Mindfulness-based stress reduction (MBSR) is an 8-week programme, which includes meditation (breath awareness, focused attention), body scan (awareness of sensations in the body) and yoga. It was

originally developed by Dr. Jon Kabat-Zinn in 1979, to help people cope better with difficulties that may cross their path, and to be generally more at ease in life.

As with many complementary therapies, anyone can call themselves a mindfulness practitioner. Be aware of this when you look for a mindfulness course. Some hospitals offer a mindfulness programme.

Is it safe?

Mindfulness practice is considered to be safe for breast cancer patients, although in the case of depression, mindfulness can have a negative impact. You are advised to discuss this with your psychologist or psychiatrist before starting a mindfulness course.

Scientific evidence for MBSR?

There is no scientific data available suggesting that MBSR can treat or cure cancer.

However, there is a great deal of research done on MBSR and its effects on a psychological (mental) and physical level, including in breast cancer.

The studies in breast cancer have shown that MBSR is an effective method to improve your mental health: it could decrease symptoms of depression, anxiety and stress, and increase your mood and overall quality of life.

Some studies indicate that there could also be benefits in relation to your immune system, chronic pain and sleeping problems, but further research is needed to draw firm conclusions about the effect on physical health. ■

Natural products as food supplements

What is a natural product?

Natural products are substances found in nature. A large number of natural products have a pharmacological (or biological) activity, which means that they could have a beneficial or adverse effect on living matter.

Living matter can refer to any living organism, such as a plant, herb, cell, organ etc.

A term you may come across in this context is phytotherapy, which is also referred to as herbal medicine. It means the treatment of diseases and medical conditions with the use of herbs.

By definition, a supplement is intended to supplement your diet when needed. In a balanced diet, all essential nutrients (vitamins, minerals, fibers, amino acids, sugars, and fatty acids) are sufficiently present, and there is no need to take any supplements. However, if you have cancer, your diet may not be ideally balanced due to, for example, side effects such as nausea, diarrhoea and loss of appetite. In this case, your diet may not include sufficient intake of all nutrients. Consequently, supplements may be required. You can ask your doctor to analyse your blood, and if there are deficiencies he/she will prescribe specific supplements.



Why natural does not mean safe

Natural products comprise a wide variety of items, such as dietary supplements, herbal supplements/phytotherapy and vitamins. Many people think that because these products are found in nature they are automatically safe.

This is far from the truth. When added to another treatment you are taking, some natural products can interfere with the other medicine in your body, and make it less effective. A well-known example is the herb St. John's Wort (*Hypericum perforatum*), which is used by some people as a mood lifter. St. John's Wort may cause certain anticancer

drugs to become less effective. Even some vitamins can have unwanted effects in your body. For example, there are research studies showing that too high a dose of some vitamins may interfere with certain chemotherapies and radiation. Too much of any vitamin is not safe, even in a healthy person.

Please be aware that supplements do not have to be approved by any government before being brought to the market; nor do they require a prescription. Therefore it is up to the user to differentiate between those that are harmful and those that are safe.

To conclude: With any complementary therapy, it is important to tell your oncologist and/or doctor if you are taking, or thinking of taking, any supplements – no matter how harmless you think they are. ■



What should I keep in mind if I want to buy a supplement?

A wide range of supplements is available on the market, with varying claims. Some claims refer to supposed anticancer properties of supplements, making them very popular with cancer patients.

Always be wary of such claims; often they are not supported by scientific research. In general, cancer patients take supplements for some or all of the following reasons:

- › Herbal medicines, sold as supplements, are claimed to have the ability to fight cancer
- › Antioxidants (see page 30) are thought to offer protection against cell damage
- › Supplements are said to enhance the immune system or to be anti-inflammatory
- › Supplements are said to improve the effect of conventional treatment

It is very important to understand the differences between a supplement and a drug (approved medicine). The main differences are:

- › **Quality/Safety:** By law, marketed drugs need to be produced and packaged under strict conditions. Additionally, the packaging leaflet must include full information on the dosing and intake schedule, the side effects, contraindications (special conditions under which using the drug is dangerous) and possible interactions with other drugs.

For supplements, the rules are not the same. The main difference is that for supplements there is no control over the final product, which means that you cannot be certain how much of the actual substance(s) is in the supplement.

- › Supplements bought from an unknown source through certain manufacturers and websites could be tainted with germs, pesticides, poisonous heavy metals etc.

“ It is very important to understand the differences between a supplement and a drug (approved medicine) ”

As mentioned above, they could also contain more, less or even none of the supposed substance(s). Some herbal supplements have even been found to contain prescription drugs. These things could all cause severe health problems.

- › **Efficacy:** : Supplements do not need to undergo the demanding scientific testing that drugs do to say how effective they are. As a result, efficacy statements for supplements are often false and exaggerated.

It may be quite difficult to ascertain whether or not a certain supplement is trustworthy. When buying supplements outside a pharmacy – for example on the internet – please keep in mind the following:

› *A reliable supplier will clearly display the contact information of the manufacturers on their website, packaging or information leaflet.*

› *There should be clear information about the ingredients of the supplement. Never trust 'secret' ingredients.*

› *Never trust promises of cures for breast cancer. So far, no supplements have been scientifically proven to cure any type of cancer.*

Having said this, you should always try to buy supplements in your pharmacy. A pharmacist is responsible for the supplements he or she sells, which will make it less likely you will get a fake or tainted supplement. ■

Popular natural products

Homeopathy



What is it?

The central principle of the homeopathic treatment is that 'like cures like', this means that a substance that causes certain symptoms can also help to remove those symptoms. Practitioners believe that the more a substance is diluted, the greater its powers to treat symptoms. Many homeopathic remedies consist of substances that have been diluted many times in water until there is none or almost none of the original substance left. Homeopathic remedies are often made from natural substances – e.g. plants, animals or minerals.

Does it work?

Homeopaths claim that by using homeopathy the body is stimulated to heal itself. Homeopathy is thus advocated for all human conditions. In cancer, it is mostly used for palliative and supportive care. There is no solid evidence, indicat-

ing that homeopathy could play an important role as a supportive therapy in integrative oncology (combination of conventional and complementary treatment). Recent trials, of homeopathic remedies in combination with standard therapy, suggest that the overall health status and wellbeing of cancer patients can be improved with homeopathic treatment. Although additional studies are needed to validate the beneficial effect of homeopathy. ■

Cannabis Oil



What is it?

Cannabis Oil is extracted from marijuana and/or hashish, and is extremely popular amongst cancer patients, including patients suffering from breast cancer.

Is it safe?

The main psychoactive component of cannabis is tetrahydrocannabinol (THC). Since there is no standardised way of preparing cannabis oil, and the makers use a random assortment of marijuana plants, the THC content varies tremendously. Consequently, there is no control over the quality of these oils; patients often make it themselves, or buy it from someone who makes it. There is no way of knowing exactly what is in the oil,

or in what dose. Therefore it is not possible to be sure that the use of cannabis oil is safe.

Does it work?

It is important to realise that the cannabis oil promoted on the internet is not the same as medicinal cannabis, for which some scientific evidence exists in relation to the easing of side effects, such as nausea, vomiting and pain.

There is no scientific evidence whatsoever for the use of cannabis oil as a treatment for breast cancer and/or its side effects. ■

Curcumin



What is it?

Curcumin is the most important component of the spice turmeric (*Curcuma longa*), a herb belonging to the ginger family. It has been suggested that curcumin has anticancer properties and prevents cancer. Besides the use of turmeric in Indian cooking, it has been used for many centuries in Indian traditional medicine (Ayurveda) to treat a variety of illnesses, such as infections of the bile duct, gall bladder and liver, as well as inflammatory diseases. Numerous commercial products containing *Curcuma longa* extract are available.

Does it work?

A limiting aspect of the use of curcumin is that it is not well absorbed by the body. Several efforts to get past this problem are ongoing. Meriva® (an example of a food supplement containing curcumin that is better absorbed by the body than regular curcumin)

seems to be able to reduce the side effects of chemotherapy and radiotherapy. In two clinical trials, patients with all types of cancer were shown to have a better quality of life when taking the Meriva® food supplement together with either chemotherapy or radiotherapy, and had fewer side effects.

So far it has not been scientifically proven that curcumin can cure or help cure any type of cancer.

Some clinical trials have reported that curcumin could help reduce radiation dermatitis (an inflammation of the skin caused by radiotherapy) in breast cancer patients. ■

Body-based and manipulative therapies

Manipulative and body-based therapies are those that involve physical manipulation and/or movement of parts of the body, using for example hands, feet or devices.

These therapies can help patients to cope with side effects, and therefore result in a better quality of life. Some examples are chiropractic or osteopathic manipulation, massage and foot reflexology.



Popular body-based and manipulative therapy – Acupuncture

What is it?

Acupuncture involves the application of needles, only slightly thicker than a hair, to certain places on the skin. These places on the skin are called acupuncture points (or acupoints).

Acupuncture has been a part of traditional East Asian medicine for about 2000 years, and arrived in Europe some 300 years ago. The most common forms of acupuncture used in Europe include body acupuncture, auricular acupuncture (stimulation of specific points on the ear) and scalp acupuncture (stimulation of specific points on the head).

Is it safe?

When performed by an experienced practitioner, acupuncture is generally safe, with few side effects.

Does it work?

There is no scientific evidence that acupuncture can cure or help cure cancer. Some high quality trials have revealed that acupoint stimulation, to a specific location above the wrist, could help with nausea and vomiting caused by chemotherapy in breast cancer patients.

Early breast cancer patients are often treated with so called Aromatase Inhibitors (AIs) like anastrozole, exemestane or letrozole. These aromatase inhibitors can cause joint pain (arthralgia). Although the results of trials investigating the effect of acupuncture

on joint pain caused by AIs have not been conclusive, they point towards a positive effect. More research is needed to confirm these conclusions.

Studies suggest that acupuncture can be very helpful for reducing nausea and vomiting, as well as hot flushes that may arise if you are prescribed hormonal therapy. Acupuncture is successful at promoting relaxation, reducing stress, and diminishing pain. ■

“ Acupuncture is successful at promoting relaxation ”

Physical activity and maintaining a healthy body weight

The importance of physical exercise, both during and after cancer treatment, is being increasingly demonstrated.

According to The American College of Sports Medicine, doing some physical activity or exercise, during and after treatment for cancer, is not only safe and feasible but also has beneficial effects on the physical, emotional and functional well-being of patients. It decreases side effects of cancer treatment, such as fatigue, loss of muscle mass, weight gain, loss of bone density (which can lead to an increased risk of osteoporosis), incontinence, pain, decreased heart function, anxiety and depression.

The time when doctors advised their patients to rest as much as possible, during breast cancer treatment and after, is definitely over.

The effect of physical activity on breast cancer

Studies conducted in breast cancer survivors have shown that patients who were regularly physically active, before and after treatment, had a lower risk of relapse and a better chance of survival than patients who were not physically active – especially when combined with a healthy diet.

Most women put on weight following breast cancer treatment – mainly due to an increase in body fat.

Most research points to a decrease in physical activity and exercise as the primary reason.

It is therefore important to keep as physically active as possible, both before and after treatment. ■



Weight control

According to recent studies, patients with breast cancer who are overweight (BMI greater than 25 kg/m²) or obese (BMI greater than 30 kg/m²), have a lower survival rate than patients with a healthy body weight.

More and more evidence is emerging that suggests it is feasible and safe for overweight or obese pa-



tients to lose weight during breast cancer treatment. For obese patients, it is recommended they lose around 5-10% of body weight. It is important to do some physical exercise and resistance training – so as to not lose muscle strength, and to maintain healthy bones.

Safe weight loss can be achieved by combining a healthy diet with sufficient physical activity (tuned to a person's specific needs) under supervision of a physiotherapist, dietician, doctor or otherwise professionally qualified person. ■

Is it OK to do some physical exercise with lymphoedema?

A common side effect of breast cancer treatment is lymphoedema. Lymphoedema is caused by the disruption of the lymphatic system, leading to a build-up of fluid and thus swelling of certain parts of the body, such as the arm, shoulder, neck, or chest. If this happens as a result of the treatment for breast cancer, it is called breast cancer-related lymphoedema, or BCRL.

In the past, exercising with lymphoedema and during breast cancer treatment was thought to be unsafe. However, more recent extensive research shows that not only is exercising with lymphoedema safe, but may be beneficial. Studies have shown that specific exercises can decrease the severity of swelling, improve muscle strength and increase general physical well-being. Certain types of exercise may actually prevent patients from getting lymphoedema.

It is advised that you start exercise slowly, increasing the intensity and frequency over time, and that you do this under the supervision of a doctor, physiotherapist or otherwise qualified practitioner.

Are there guidelines on physical activity for breast cancer?

No guidelines currently exist to recommend the amount and type of exercise or physical activity for breast cancer patients.

strength/resistance training sessions – that is exercises that stimulate the muscles to contract, such as weight lifting, bodybuilding etc. Resistance training (RT) may help to reduce muscle loss and to recover lost muscle mass, as well as improve muscle function, bone mineral density, physical perfor-

“ Safe weight loss can be achieved by combining a healthy diet with sufficient physical activity ”

As patients vary (in terms of age, stage of disease, other health issues, physical function, etc.) it may be impossible to ever have one standard approach for everyone. Any exercise programme needs to take into account patients' functional ability and exercise habits before they became ill.

In 2010, The American College of Sports Medicine reviewed scientific research done on the safety and effects of physical exercise during and after cancer treatment. As a result, they recommend the same level for cancer patients (including breast cancer patients), as for healthy people.

In addition, they recommend 10 minutes, 2-3 times a week, of

› 150 minutes a week (5x30 minutes) of moderate-paced activity, such as walking, gardening, yoga etc.

› Or 75 minutes a week of more vigorous, intensive physical (aerobic) activity such as running, jogging, football, swimming etc.

› Or a combination of these.



mance, fatigue and cardiovascular health. Please note that any upper body training you undertake should be done with great care and should be built up very slowly.

Before you start any exercise programme, it is important to discuss this with your doctor or oncologist because there may be some exercises that will be harmful in your specific situation. ■



diet & nutrition

More and more research is being done on lifestyle changes in cancer patients – for example, in relation to nutrition and physical activity. The results of these studies show that a healthy lifestyle, including a healthy body weight (BMI less than 25 kg/m²), good eating habits and regular physical activity, can influence the prognosis and the quality of life of breast cancer patients.

A balanced diet before, during, and after cancer treatment can help you feel better and stay healthier. Healthy eating habits and good nutrition can help cancer patients to deal with the effects of cancer and its treatments. Some cancer treatments are more effective when the patient gets a balanced diet including enough calories and proteins. In some cases, this will lead to a better prognosis and quality of life because the patients will, for example, be able to better tolerate certain treatments, recover better after an operation, or be more resistant to infections/inflammation.

For many patients, the effects of breast cancer and its treatments make it harder to eat well. Breast cancer treatments that affect nutrition include surgery, radiation and chemotherapy. They may cause problems such as nausea, vomiting, loss of appetite, infections and pain in the mouth, diarrhoea, constipation, changes in smell etc.

It is very important to tell your doctor, if one of these side effects appears. Together with your doctor/dietician you can adapt your diet and, if needs be, nutritional supplementation or medication can be prescribed.



Sometimes it is better to eat frequent, small meals instead of normal meals three times a day, and to discuss with your dietician what kind of food you enjoy or can digest easily.

If you start having eating problems, it is important to talk to your doctor/dietician as soon as possible because, when the body does not get (or cannot absorb) the nutrients needed for health, this results in malnutrition or malnourishment, which can lead to weight loss, anorexia and cachexia.

Anorexia and cachexia

Anorexia, whatever the cause, is a condition in which the patient loses his/her appetite. It can be as a result of the cancer itself, of

the cancer treatment or for other reasons. Cachexia is a condition caused by the disease itself, in which the patient loses weight and muscle, is weak and tired and suffers loss of appetite. It is also called wasting syndrome.

The problem with cachexia is that once it starts it is very difficult to reverse. Even if the patient improves his/her diet and eats more, the condition will persevere.

This is why it is very important to inform your doctor/dietician immediately if you have any eating problems. He/she can then adapt your diet or prescribe nutritional supplementation or in some cases medication to prevent cachexia/anorexia. ■

“ If you start having eating problems, it is important to talk to your doctor/dietician ”

Popular diets and foods

Conducting clinical research, on the effects of diets and nutrition on cancer, is challenging for many reasons.

One reason is that food intake (how much, what type, how often) varies between breast cancer patients. To really study the effect of a particular nutrient or diet, researchers would need to control everything the participants eat, including how much and when. Also, each person's body digests food differently, depending on age, weight, genetic factors etc. The effects of cancer treatments on the body make these variations even greater.

Most of the trials on nutrients and diets examine the effect on the prevention of cancer, which is not the topic of this guide. Very limited scientific research has been done on the effects of nutrients and diets on the cancer itself, during cancer treatment.

Below, we highlight some of the better known and more popular nutrients and diets that are claimed to have anticancer properties.

Alcohol

Although there is evidence that even light alcohol drinking increases the risk of developing breast cancer, moderate, post-diagnosis alcohol consumption is unlikely to have a major adverse effect on the survival of women with breast cancer. However, breast cancer patients should avoid drinking too much alcohol which means no more than 2 glasses of beer (500 ml), wine (200 ml) or spirits (50 ml) per day, because there seems to be a relationship between level of alcohol consumption and breast cancer mortality and recurrence before and after treatment. ■

Soy foods

Soy foods are rich in isoflavones, certain of which are said to possibly help fight breast cancer. There has been some concern about soy food consumption amongst breast cancer patients because of particular properties of these isoflavones. They have oestrogen-like effects, which could, theoretically, have an effect on breast cancer and might interact with tamoxifen (a breast cancer treatment).

However, researchers have been able to reassure doctors, since there has been no evidence found that eating soy could be harmful for breast cancer patients. Moreover, the studies have shown that eating moderate amounts of soy food is associated with fewer deaths and less disease recurrence, for certain breast cancer types in patients. Very little research has been done regarding soy food products in relation to the side effects of breast cancer treatments, and no conclusions have been drawn in this respect. Please note that this section does not refer to soy supplements, but merely about soy in food. ■

Antioxidants

Antioxidants are substances that may help prevent cell damage caused by chemical reactions with oxygen. As cell damage plays a role in cancer development, there is a theory that antioxidants could help prevent cancer, but this theory has not so far been confirmed by researchers.

It is also not known whether antioxidants increase or decrease the effect of (breast) cancer treatment with certain types of chemotherapy and radiation. Examples of food, in which antioxidants can be found, include grapes (blue, purple and red), berries, artichokes, beans, green tea. Examples of antioxidants that can be bought as supplements include Vitamins A-C-E, zinc, selenium and melatonin.

Is it safe for me to take antioxidants during breast cancer treatment?

Some say that antioxidants could reduce side effects – by protecting the normal cells against damage



caused by chemo and radiation therapy – which will allow the patient to tolerate the treatment for longer. However, others say that antioxidants might also prevent damage to cancer cells, thereby helping the cancer cells survive – which is of course exactly the opposite of what we want. The correct answer remains unclear and research is ongoing, including in breast cancer.

Keeping this in mind, and considering the fact that many food supplements contain a much higher dose of antioxidants than the recommended intake, it may not be advisable to take them during chemotherapy and radiation. Until more scientific evidence is available, it is best to limit your antioxidant intake to that from food, instead of taking supplements, while on breast cancer treatment. ■

Mediterranean diet

The Mediterranean diet is a way of eating based on traditional foods (and drinks) of the countries around the Mediterranean Sea. The building blocks of the Mediterranean diet are foods that are low in saturated fat, rich in healthy oils and packed with fresh fruits and vegetables.

There has been only one study done on the effect of a Mediterranean diet on breast cancer. The study revealed that, after diagnosis with breast cancer, following a Mediterranean diet can reduce the risk of death. This can be explained by the fact that women with breast cancer have a higher risk of cardiovascular problems, due to the cancer treatment.

Following a Mediterranean diet could reduce those cardiovascular problems.



› *Eating primarily plant-based foods, such as fruits and vegetables, whole grains, beans & nuts*

› *Seasoning food with herbs and spices instead of salt*

› *Using healthy plant-based fats, such as olive oil, instead of butter*

› *Limiting the intake of red and processed meat and eating more poultry (chicken, turkey etc.) and fish*

The image shows three European Union flags, each with twelve yellow stars on a blue field, waving on silver poles. The flags are in the foreground, slightly out of focus. In the background, a large, curved building with many windows is visible under a clear blue sky. The overall scene is bright and clear.

EU – Regulations for non-conventional treatment

Each EU country has its own set of regulations regarding non-conventional treatment.

Most countries in northern Europe have a more or less unregulated system, while many of the countries in southern and eastern Europe have, to a large degree, regulated all health practices. The use of different types of non-conventional treatments varies from region to region in Europe:

For example, some treatments that have a long-standing tradition in central Europe may be unknown in the UK and Scandinavia, and vice-versa.

Therefore, it may be difficult to get certain types of non-conventional treatment in another country.

For example, if you cross European borders in search of non-conventional treatments, you may encounter considerable variation in the professional background of apparently identical practitioners. In one country they may have to be medical doctors, in another anyone may be able to do it. Also, the reimbursement system may differ substantially.

If you were to experience a side effect, or get hurt by the treatment, protection or compensation would be very different, depending on which country you were in.

To summarise, you might encounter the following challenges if you were to seek non-conventional treatment abroad:

› A wide variation in treatments and providers available per country.

› Varying and unpredictable levels of professional competence from the practitioner, for similar treatments.

› Very differing systems of quality of the services provided.

› Unpredictable systems of reimbursement

› Limited and complex recourse to complaint.

Reimbursement of non-conventional treatment

In many countries, non-conventional treatments are not included in the health care system, and will not (or occasionally only partly) be reimbursed. Reimbursement of non-conventional treatments can

also be refused because regulations in the country you come from differ from those in the country of treatment.



Belgium, The Netherlands and France

Belgium

In Belgium, there is no legal framework for the practice of non-conventional treatments. No claims are allowed against non-conventional treatments for the cure of cancer.

Non-conventional treatments are not reimbursed by compulsory health insurance (RIZIV/INAMI), but several health insurance funds incorporate certain non-conventional treatments in their voluntary health insurance.

The Netherlands

In the Netherlands, practising non-conventional treatment is legal, for both medically and non-medically qualified professionals. It is, however – fortunately – punishable to inflict harm upon a person's health.

Non-conventional treatments are not covered by basic health insurance, but health insurers cover some non-conventional treatments as either additional 'free' benefits, or cover them by complementary Voluntary Health Insurance.

France

There is no specific law on non-conventional treatments in France.

Acupuncture consultations and homeopathy consultations (both consultations need to be carried out by a licensed medical doctor) are reimbursed by the national insurance system (acupuncture by national and private insurance).

Homeopathic treatments are partly reimbursed (30%) by the national insurance system.



CLINICAL *trials*

Medical research studies involving human beings are called clinical trials. A clinical trial is conducted to find out whether a new treatment is safe, whether it works (efficacy), works better than the current available treatment or helps you feel better.

When researchers think that they have found a promising treatment they cannot immediately treat patients with it. If it is a brand new treatment, they will first test it in the test tube. If results are encouraging, they will test the treatment on animals (these studies are highly regulated to avoid unnecessary suffering to animals). If results of the tests on animals are encouraging, they will start testing the new treatment in humans, i.e. in a clinical trial.

Classically, clinical trials are divided into different stages or phases, for example phase 1, phase 2. The higher the phase, the further on the new treatment is in the research process.

This first step in humans is called a phase 1 clinical trial. In this kind of clinical trial, researchers will test whether the treatment is safe. The main thing that researchers will look at in Phase 1 trials is whether there are any serious side effects. Next to that, they may want to identify the best dose.

If results are encouraging, phase 2 and phase 3 clinical trials will follow, to test if the treatment works (efficacy).

Clinical trials are strictly regulated by national and international legislations and regulations because the experiments are done in humans. The main goal of these regulations is to protect the people participating in clinical trials and to ensure that patients are informed of the possible risks and benefits. An institutional review board, often called an ethical committee, will check if everything is in place to ensure patients' safety and confidentiality. They will also check if the information provided to participants is complete and understandable. ■



When will patients typically participate in a clinical trial?

Usually, doctors propose that their patients participate in a clinical trial either right after their diagnosis or later, after treatment. This will depend on the clinical trial. Patients can also tell their doctors that they want to participate in clinical trials, or they can search for clinical trials themselves.

Before your participation in a given clinical trial can start, two major things have to be done:

1. Eligibility Check

Each clinical trial has its own entry conditions that are called eligibility or inclusion criteria. These criteria must be fulfilled in order for a patient to participate in the trial. For example, participants must have a specific cancer type and stage, be of a certain age etc. Your doctor will have a checklist of all criteria and will verify them for you. Sometimes this requires additional examinations, such as blood tests.



2. Informed Consent

Informed consent means that you agree to participate and have been informed of the goal of the clinical trial, its risks and your rights. Your doctor will explain all of this to you and will give you written information as well. You will get time to think about it, and you will have the chance to ask questions before agreeing to participate. Once you agree, your doctor will ask you to sign an informed consent form.

It is very important to remember, that one of your most important rights as a participant, is that you can stop participating at any time without giving any reason. This will have no consequence on any standard treatment you are to receive after you leave the trial. You will continue to be treated according to the established standards of care.

Once your doctor has verified that you are eligible and you have signed an informed consent form, you will be enrolled in the clinical trial. ■

What are the possible benefits and risks?

What are some of the possible benefits of participating in clinical trials?

You should not assume that the new treatment will be better than the standard treatment. This is why the new treatment is being tested in the first place.

However, there are benefits, of which we list a few below:

› You may have access to a promising treatment, which is not yet available outside of a trial

› The new treatment may work better than the standard treatment

› You will be monitored carefully by doctors, probably more closely than when receiving standard treatment

› The clinical trial is an experiment and its results may be helpful for other cancer patients, if not helpful for you. It will either allow other patients to benefit from a new and useful treatment or avoid more patients taking a useless or harmful new treatment.

What are the possible risks of participating in clinical trials?

› The new treatment may not have any added value



› The new treatment may have some side effects that can range from minor and reversible side effects to life-threatening side effects. Some side effects can also appear weeks, months or even years later and include damage to important organs – such as heart or kidney – or the development of a second cancer. In phase 3 clinical trials you will not usually know whether you are in the group that is receiving the new treatment or not.

How to find a clinical trial

There are several ways in which you might find a trial suitable for you:

- › Your doctor proposes it to you.
- › You search for a clinical trial in the database www.clinicaltrials.gov or you ask the Anticancer Fund for support via info@anticancerfund.org.



REPURPOSING

existing

DRUGS

What is it?

Many existing drugs that are on the market for health issues other than cancer – for example arthritis or diabetes – have been shown, in scientific research, to have anticancer properties.

This means that more extensive research could show that these drugs might work as an anticancer treatment. In addition to drugs that may be able to attack the cancer itself, there are drugs that may help your current cancer treatment to work better.

Using existing drugs as a treatment for a disease other than that

which it was intended for, is called repurposing drugs. Other terms, for repurposing drugs, are repositioning drugs, therapeutic switching, drug recycling or drug retasking. When you take repurposed drugs that are not licensed for your particular disease, it is called off-label use.

An example of a repurposed drug being researched for breast cancer is metformin. Metformin is a drug that is currently used to treat diabetes. Clinical research shows that metformin could decrease or change the ability of breast cancer cells to grow.

Additionally, it is possible that metformin could work with other treatments, to keep breast cancer from recurring. Further research is now being conducted to shed light on these early findings. ■

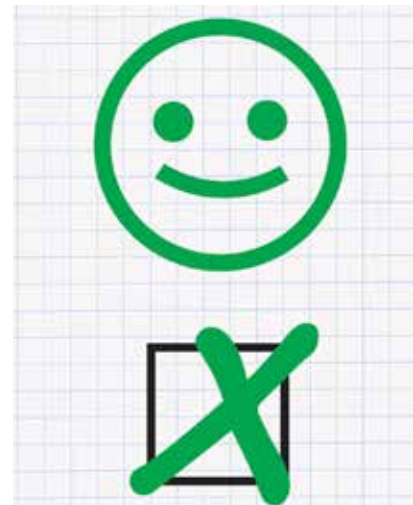
Advantages

One great advantage of drug repurposing, over traditional drug development, is that the drug has already been through a good deal of scientific testing regarding safety, quality etc., (in order to obtain marketing authorisation for its original purpose).

This considerably reduces the amount, and therefore the cost, of scientific testing still to be done. Moreover, the risk of failure is reduced because its safety is already well-known.

Another advantage is that medicines that are already approved and in use tend to be cheap.

Altogether, it is much more efficient to repurpose existing drugs than to design and develop a whole new drug. However, due to a lack of commercial interest from pharmaceutical companies, funding to achieve this will need to come from not-for-profit organisations worldwide. ■



Further information

If you are interested to find out which repurposed drugs are currently being investigated for use in breast cancer, please visit:

- › www.redo-project.org
- › www.global-cures.org

Glossary

Acupoints:	acupuncture points (acupoints) are specific points on the body that are targeted by acupuncture treatment
Alternative therapy:	a therapy intended to be used instead of conventional treatment
Anorexia:	loss of appetite and/or an aversion to food, whatever the cause
Anti-inflammatory:	reducing inflammation
Aromatase inhibitor:	a class of drugs that blocks a protein called aromatase, which is important in the body's production of oestrogens. It is used to treat specific types of breast and ovarian cancer
Arthralgia:	joint pain – in this context caused by treatment with aromatase inhibitors
BCRL:	breast cancer-related lymphedema – see lymphoedema
Biological therapy:	biological therapies act on processes that happen in cells in our body. These therapies may stop the division and growth of cancer cells, seek out cancer cells to kill them or stimulate the immune system to attack cancer cells.
Body Mass Index (BMI):	the Body Mass Index is a statistical means of measuring body weight, based on a person's weight and height. It can be calculated by dividing weight, in kilograms, by the square of the height, in meters. It is used to calculate whether someone is overweight
Cachexia:	a condition of weight and muscle loss, of being weak and tired and having loss of appetite, due to the disease itself
Chemotherapy:	the treatment of cancer by the use of chemical substances
Clinical trial:	a clinical trial is a research study that tests how well new medical approaches work in humans
Conventional therapy:	therapies that have been approved by regulatory authorities, and are now used in standard healthcare - also often called traditional, standard or classical therapies
Constipation:	means your bowel movements are difficult or happen less often than normal
Efficacy:	the ability of an intervention – for example, a drug or surgery – to have the desired beneficial effect (e.g. killing cancer cells)
Endpoint:	an event or outcome that can be measured objectively, to decide whether an intervention being studied – for example, a drug or surgery – is beneficial

Oestrogen:	a female sex hormone responsible for development and regulation of the female reproductive system and secondary sex characteristics (breast growth, voice, hair growth etc.)
Evidence-based medicines	an approach to medical practice intended to optimize decision-making by the use of evidence from well-designed and conducted research
HON code:	the Health on the Net Foundation Code of Conduct (HONcode) for medical and health websites. The HONcode certification is an ethical standard intended to offer high quality health information. It demonstrates the intention of a website to publish reliable and credible information
Hormonal therapy:	the use of hormones as a medical treatment. In breast cancer hormonal treatment is used for ER+ and/or PR+ tumours, i.e. when oestrogen (ER) or progesterone (PR) receptors have been detected on the cancer cells
Immune system:	your body's defence mechanism; a complex network of cells, tissues and organs that work together to defend against germs and other attacks on your body
Immunotherapy:	treatment to boost, or restore, the ability of the immune system to fight cancer, infections and other diseases
Information leaflet:	the folded leaflet that comes with the packaging of a particular drug, containing information about its dosage, frequency of intake, possible side effects, manufacturer etc.
Isoflavones:	an oestrogen – like substance made by some plants, including the soy plant
Lymphatic system:	the lymphatic system is an important part of the immune system, comprising a network of lymphatic vessels that carry a clear fluid called lymph
Lymphoedema:	a type of swelling caused by the build-up of lymph in your body's soft tissues (muscles, tendons, fat, and blood vessels), usually in the arms or legs
Malnutrition:	the condition that occurs when the body does not get enough nutrients
Non-conventional treatment:	any medical system, practice, or product that is not part of the established (conventional) therapy or standard of care
Off-label use:	the intake of a drug for a disease or condition other than that for which it has been marketed
Peer-reviewed	peer review is the process of subjecting an author's research, or ideas, to inspection by experts in the same subject area, before a paper describing this work is published in a journal or as a book
Phytotherapy:	the treatment of diseases and medical conditions, with plants

Private clinic:	a practice or hospital (clinic) that runs for profit, and is not subsidised by any higher institution such as the government
Prognosis:	the likely course of a disease
Psychoactive component:	the element of a substance or drug that changes brain function and causes changes in perception, mood, or consciousness
Quackery:	the promotion of fraudulent or ignorant medical practices
Quality of Life:	measure of emotional, physical and social wellbeing
Radiation dermatitis:	inflammation of the skin caused by radiation therapy
Radiotherapy:	a treatment to destroy cancer cells with radiation beams
RCT:	Randomised Controlled Trial: A study in which a number of similar patients are randomly assigned to 2 or more groups, to test a specific drug or treatment. 1 group (the experimental group) receives the treatment being tested, while the other (the comparison or control group) receives an alternative treatment, dummy treatment (placebo) or no treatment.
Registered drugs:	drugs that have been authorised to be sold for a specific disease or condition
Repurposing drugs:	using existing drugs as treatment for a disease other than that for which it was intended
Safety:	analysis of the number and type of side effects caused by a certain treatment or combination of treatments
Supplement:	a product taken orally that is intended to supplement one's diet with a specific nutrient(s), for example vitamins, minerals etc.
Targeted therapies:	a type of treatment that uses drugs or other substances (such as monoclonal antibodies) to identify and attack specific mechanisms in cancer cells
Toxicity:	the level of harm caused by a particular treatment or a combination of treatments
Wasting syndrome:	another word used to describe cachexia

Colophon

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