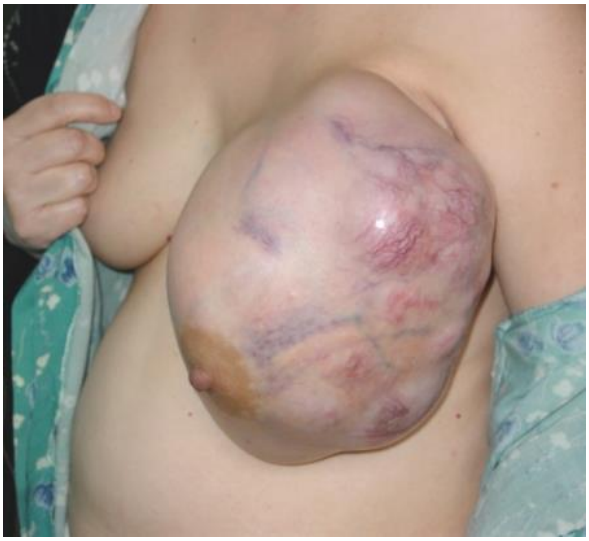
Cancer Association of South Africa (CANSA)

Research • Educate • Support

Fact Sheet
on
Phyllodes Tumours

Introduction

Phyllodes tumours [from the Greek: phullon (meaning 'leaf')], also cystosarcoma phyllodes, cystosarcoma phylloides, and phylloides tumour, are typically large, fast-growing masses that form from the periductal stromal cells of the breast. It accounts for less than 1% of all breast neoplasms.



[Picture Credit: Phyllodes Tumour]

Phyllodes tumours are a fibro-epithelial tumour composed of an epithelial and a cellular stromal component. They may be considered benign, borderline, or also malignant depending on histologic features including stromal cellularity, infiltration at the tumour's edge, and mitotic activity (having to do with the presence of dividing or proliferating cells). Cancer tissue generally has more mitotic activity than normal tissues. All forms of phyllodes tumours are regarded as having malignant potential. They are also known as *serocystic disease of Brodie*. Phyllodes tumours rarely spread outside the breast.
(Wikipedia).

Phyllodes Tumour

Although most phyllodes tumours are benign (not cancerous), some are malignant (cancerous) and some are borderline (in between non-cancerous and cancerous with a tendency to probably become cancerous). All three kinds of phyllodes tumours tend to grow quickly, and they require surgery to reduce the risk of a phyllodes tumour coming back in the breast (local recurrence).

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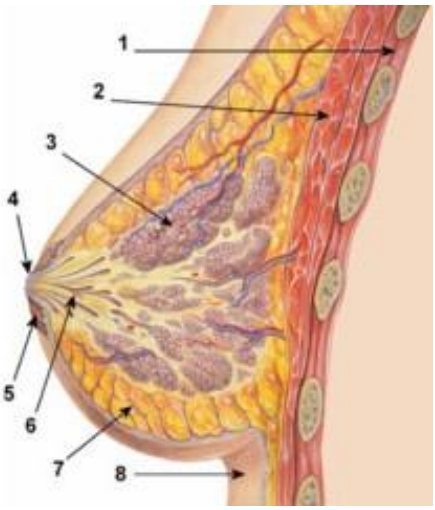
Phyllodes tumours can occur at any age, but they tend to develop when a woman is in her 40s. Benign phyllodes tumours are usually diagnosed at a younger age than malignant phyllodes tumours. Phyllodes tumours are extremely rare in men.
Unlike breast cancers called carcinomas, which develop *inside* the ducts (milk-carrying tubes) or lobules (milk-producing glands) of the breast, phyllodes tumours start *outside* of the ducts and lobules.



[Picture Credit: Female Breast]

Phyllodes tumours develop in the breast's connective tissue, called the stroma. The stroma includes the fatty tissue and ligaments that surround the ducts, lobules, and blood and lymph vessels in the breast. It may be helpful to think of the stroma as the tissue that 'holds everything together' inside the breast. In addition to stromal cells, phyllodes tumours can also contain cells from the ducts and lobules. (BreastCancer.org).

The three main types of phyllodes tumour:

- Non-cancerous (benign) tumours – these make up about 50–60% of phyllodes tumours.
- Borderline tumours – these are not yet malignant (cancerous) but are more likely to turn malignant.
- Cancerous (malignant) tumours – these make up about 20–25% of all phyllodes tumours.

(MacMillan Cancer Support).

Phyllodes tumours (PTs) take their name from the Greek word phullon because of their leaf-shaped growth pattern. Dr Carol-Ann Benn, a surgeon with a special interest in breast cancer, prefers to call them weeds, because, like weeds, they recur if not pulled out properly. "When you pull out a weed, little seeds are left behind and the weed grows back. In the case of phyllodes tumours, if they aren't excised with proper margins, they grow back even more aggressively than before."

These tumours can be benign or malignant (low-grade and high-grade), explains breast pathologist Dr Simon Nayler. Outcome and survival rates are dependent on the type of phyllodes tumour, which can only be determined after being examined microscopically. "Benign PTs never spread, but between 8% and 20% may recur in the same breast after removal," he warns.

"High-grade malignant PTs spread (metastasise) in about a quarter of all patients, with a high local recurrence of 36% to 65%. Low-grade malignant PTs lie somewhere in between, with a local recurrence of 29% to 46% and spread occurring in less than 5% of cases."

According to Professor Justus Apffelstaedt, associate professor at the University of Stellenbosch and head of the Breast Clinic at Tygerberg Hospital, phyllodes tumours account for around only 1% of all breast cancers.

“Unlike ‘normal’ breast cancer there are no identified risk factors here, nor does there seem to be a genetic predisposition. And unlike ‘normal’ breast cancer, which arises from the glandular elements of the breast, PTs are tumours of connective tissues, which is why they are called sarcomas.”

Adds Benn: “Malignant PTs do not usually spread, like normal breast cancers, to the lymph nodes. They tend to recur locally, but the more aggressive ones can spread to the lungs and liver, and some are so large (up to 30cm in size) that complete removal of the breast and part of the chest wall is required.”

As with any form of cancer, the earlier the diagnosis, the better the prognosis, with the vast majority of PT patients having a very good chance of survival, says Nayler.

“Death due to the tumour is 0,3% for benign PT, 6,6% for low-grade malignant tumours and 20% for high-grade malignant tumours.”

However, due to its rapid growth, even in benign cases, a phyllodes tumour can cause extensive nerve and other damage, which is why it’s important not to let the fear factor prevent you from seeking expert advice, recommend the experts.
(Longevity).

Incidence of Malignant Phyllodes Tumour in South Africa
The National Cancer Registry (2013) does not reflect the incidence of Phyllodes Tumour. However, according the National Cancer Registry (2013) the following cases of histologically diagnosed breast cancer cases in South Africa among women was as follows:

According to the National Cancer Registry (2013) the following number of breast cancer cases in women was histologically diagnosed during 2013:

Group 2013	Actual Number of Cases	Estimated Lifetime Risk	Percentage of All Cancers
All females	8 132	1 : 28	22,22%
Asian females	363	1 : 19	35,03%
Black females	3 341	1 : 51	21,37%
Coloured females	1 098	1 : 20	22,07%
White females	3 331	1 : 11	20,98%

Frequency of Histologically Diagnosed Cases of Breast Cancer
According to the National Cancer Registry (2013), the frequency of histologically diagnosed cases of breast cancer in women in South Africa is as follow:

Group 2013	0 to 19 Years	20 to 29 Years	30 to 39 Years	40 to 49 Years	50 to 59 Years	60 to 69 Years	70 to 79 Years	80 + Years
All females	2	115	777	1 722	1 900	1 783	1 162	325
Asian females	0	5	27	68	89	78	53	22

Black females	2	71	418	790	779	588	351	176
Coloured females	0	13	88	230	277	240	144	72
White females	0	23	217	825	717	824	585	278

Signs and Symptoms of Phyllodes Tumour

These tumours will usually present as a smooth lump felt beneath the skin. The breast may become red or warm to the touch. These tumours can grow very fast, so it is important to have them evaluated as soon as possible. Symptoms can also mimic those of other types of breast cancer.
(Johns Hopkins Medicine).

Differential Diagnosis of Phyllodes Tumour

The differential diagnosis of Phyllodes Tumour include:

Juvenile Fibroadenoma	Low Grade Phyllodes Tumour
No leaf-like architecture	Prominent leaf-like architecture
No condensation around ducts	Stromal condensation around ducts
Does not infiltrate	May infiltrate surrounding breast

The histologic border between these two is not always sharp

Juvenile Fibroadenoma	High Grade Phyllodes Tumour
No stromal atypia	Atypical stroma
Stromal mitotic rate < 3/10 hpf	Elevated stromal mitotic rate
No stromal overgrowth	Stromal overgrowth
Does not infiltrate	May infiltrate surrounding breast

Stromal overgrowth defined as at least one low power field (40x total magnification) composed entirely of stroma

Fibroadenoma	Low Grade Phyllodes Tumour
Lacks significant stromal hypercellularity	Hypercellular stroma is prominent
No stromal overgrowth	May have stromal overgrowth
No leaf-like architecture	Prominent leaf-like architecture
No condensation around ducts	Stromal condensation around ducts
Does not infiltrate	May infiltrate surrounding breast

The histologic border between these two is not always sharp

Metaplastic Carcinoma	Phyllodes Tumour
Spindled component may be positive for high molecular weight keratin or p63	Stromal component negative for high molecular weight keratin and p63
Epithelial component is malignant	Epithelial component is benign
Squamous differentiation may be present	No squamous differentiation

Pure Sarcoma of the Breast

- Very rare
- The presence of an epithelial component defines phyllodes tumour

Fibromatosis

- Bland spindle cells
- Stellate configuration
- Absence of intrinsic epithelial component
    - May entrap normal breast lobules

Myofibroblastoma

- Resembles solitary fibrous tumour
- Lacks intrinsic epithelial component

(Stanford School of Medicine).

Diagnosis of Phyllodes Tumour

Phyllodes Tumour is diagnosed as follows:

Like other less common types of breast tumours, phyllodes tumours can be difficult to diagnose because doctors do not encounter them all that often. A phyllodes tumour also can look like a more common type of benign breast growth called a fibroadenoma. A fibroadenoma is a solid, growing lump of normal breast cells that is the most common kind of breast mass, especially in younger women.

Two key differences between fibroadenomas and phyllodes tumours are that phyllodes tumours tend to grow more quickly and develop about 10 years later in life — in the 40s as opposed to the 30s. These differences can help doctors distinguish phyllodes tumours from fibroadenomas.

Diagnosing phyllodes tumours usually involves a combination of steps:

- A physical (clinical) examination of the breasts. The doctor may be able to feel the lump in the breast, or a patient may feel it herself during a breast self-examination
- A mammogram to obtain X-ray images of the breast and locate the tumour. On a mammogram, a phyllodes tumour appears as a large round or oval mass with well-defined edges. Sometimes the tumour might look like it has rounded lobes inside it. Calcifications can show up as well. Calcifications are tiny flecks of calcium - like grains of salt - in the soft tissue of the breast. The doctor likely will need to do additional testing to confirm that the lump is a phyllodes tumour
- Ultrasound to obtain sound-wave images of the breast. The images form as the sound waves are ‘echoed back’ by the tissue. On ultrasound, phyllodes tumours look like well-defined masses with some cysts inside of them
- MRI to obtain additional images of the tumour and help in planning surgery
- Biopsy to take samples of the tumour for examination under a microscope. Although imaging tests are useful, biopsy is the only way to tell if the growth is a phyllodes tumour. The doctor can perform one of two procedures:
    - core needle biopsy, which uses a special hollow needle to take samples of the tumour through the skin
    - excisional biopsy, which removes the entire tumour

Some experts believe it is better to use excisional biopsy if a phyllodes tumour is suspected. Examining the whole tumour is often necessary to make the right diagnosis. The smaller tissue samples taken during core needle biopsy may not be enough to confirm that a lump is a phyllodes tumour.
A pathologist then examines the tumour tissue under a microscope to make the diagnosis. He or she also classifies the phyllodes tumour as benign, borderline, or malignant. In a benign tumour:

- the edges are well-defined
- the cells are not dividing rapidly
- the stromal cells (connective tissue cells) still look somewhat like normal cells
- there is not an 'overgrowth' of stromal cells - there are epithelial cells (the types of cells that line the ducts and lobules) as well

In a malignant tumour:

- the edges are not well-defined
- the cells are dividing rapidly
- the stromal cells have an abnormal appearance
- there is an overgrowth of stromal cells, sometimes with no epithelial cells present at all

Phyllodes tumours are called 'borderline' if their features fall somewhere in between these two descriptions. The label 'benign' often makes people think that a condition is not harmful and may not require treatment. But benign phyllodes tumours, like malignant ones, can grow to be large in size, creating a visible lump on the breast and perhaps even breaking through the skin, causing pain and discomfort. This is why both benign and malignant tumours require treatment. The main difference between them is that malignant phyllodes tumours, especially those with lots of stromal overgrowth, may recur more quickly and have a greater likelihood of recurring outside the breast.
(BreastCancer.org).

Treatment of Benign Phyllodes Tumour

Phyllodes tumours are always treated with surgery. This may be a wide local excision. or a mastectomy, depending on the size. The specialist will discuss with the patient the type of surgery she needs.

The aim of the surgery is to remove all of the tumour and an area of healthy tissue around it, known as clear margin (border). This is because it is important to have a clear margin of healthy tissue when the lump is removed to reduce the risk of it coming back.

If a clear margin was not achieved by the initial surgery further surgery is usually recommended.
(Breast Cancer Care).

Treatment of Malignant (Cancerous) Phyllodes Tumour

Malignant phyllodes tumours are treated by removing them along with a wider margin of normal tissue, or by mastectomy (removing the entire breast) if needed. Malignant phyllodes tumours are different from the more common types of breast cancer. They do not respond to hormone therapy and are less likely than most breast cancers to respond to radiation therapy or the chemotherapy drugs normally used for breast cancer. Phyllodes tumours that have spread to distant areas are often treated more like sarcomas (soft-tissue cancers) than breast cancers.
(American Cancer Society).

About Clinical Trials

Clinical trials are research studies that involve people. These studies test new ways to prevent, detect, diagnose, or treat diseases. People who take part in cancer clinical trials have an opportunity to contribute to scientists' knowledge about cancer and to help in the development of improved cancer treatments. They also receive state-of-the-art care from cancer experts.

Types of Clinical Trials

Cancer clinical trials differ according to their primary purpose. They include the following types:

Treatment - these trials test the effectiveness of new treatments or new ways of using current treatments in people who have cancer. The treatments tested may include new drugs or new combinations of currently used drugs, new surgery or radiation therapy techniques, and vaccines or other treatments that stimulate a person's immune system to fight cancer. Combinations of different treatment types may also be tested in these trials.

Prevention - these trials test new interventions that may lower the risk of developing certain types of cancer. Most cancer prevention trials involve healthy people who have not had cancer; however, they often only include people who have a higher than average risk of developing a specific type of cancer. Some cancer prevention trials involve people who have had cancer in the past; these trials test interventions that may help prevent the return (recurrence) of the original cancer or reduce the chance of developing a new type of cancer

Screening - these trials test new ways of finding cancer early. When cancer is found early, it may be easier to treat and there may be a better chance of long-term survival. Cancer screening trials usually involve people who do not have any signs or symptoms of cancer. However, participation in these trials is often limited to people who have a higher than average risk of developing a certain type of cancer because they have a family history of that type of cancer or they have a history of exposure to cancer-causing substances (e.g., cigarette smoke).

Diagnostic - these trials study new tests or procedures that may help identify, or diagnose, cancer more accurately. Diagnostic trials usually involve people who have some signs or symptoms of cancer.

Quality of life or supportive care - these trials focus on the comfort and quality of life of cancer patients and cancer survivors. New ways to decrease the number or severity of side effects of cancer or its treatment are often studied in these trials. How a specific type of cancer or its treatment affects a person's everyday life may also be studied.

Where Clinical Trials are Conducted

Cancer clinical trials take place in cities and towns in doctors' offices, cancer centres and other medical centres, community hospitals and clinics. A single trial may take place at one or two specialised medical centres only or at hundreds of offices, hospitals, and centres.

Each clinical trial is managed by a research team that can include doctors, nurses, research assistants, data analysts, and other specialists. The research team works closely with other health professionals, including other doctors and nurses, laboratory technicians, pharmacists, dieticians, and social workers, to provide medical and supportive care to people who take part in a clinical trial.

Research Team

The research team closely monitors the health of people taking part in the clinical trial and gives them specific instructions when necessary. To ensure the reliability of the trial's results, it is important for the participants to follow the research team's instructions. The instructions may include keeping logs or answering questionnaires. The research team may also seek to contact the participants regularly after the trial ends to get updates on their health.

Clinical Trial Protocol

Every clinical trial has a protocol, or action plan, that describes what will be done in the trial, how the trial will be conducted, and why each part of the trial is necessary. The protocol also includes guidelines for who can and cannot participate in the trial. These guidelines, called eligibility criteria, describe the characteristics that all interested people must have before they can take part in the trial. Eligibility criteria can include age, sex, medical history, and current health status. Eligibility criteria for cancer treatment trials often include the type and stage of cancer, as well as the type(s) of cancer treatment already received.

Enrolling people who have similar characteristics helps ensure that the outcome of a trial is due to the intervention being tested and not to other factors. In this way, eligibility criteria help researchers obtain the most accurate and meaningful results possible.

National and International Regulations

National and international regulations and policies have been developed to help ensure that research involving people is conducted according to strict scientific and ethical principles. In these regulations and policies, people who participate in research are usually referred to as "human subjects."

Informed Consent

Informed consent is a process through which people learn the important facts about a clinical trial to help them decide whether or not to take part in it, and continue to learn new information about the trial that helps them decide whether or not to continue participating in it.

During the first part of the informed consent process, people are given detailed information about a trial, including information about the purpose of the trial, the tests and other procedures that will be required, and the possible benefits and harms of taking part in the trial. Besides talking with a doctor or nurse, potential trial participants are given a form, called an informed consent form, that provides information about the trial in writing. People who agree to take part in the trial are asked to sign the form. However, signing this form does not mean that a person must remain in the trial. Anyone can choose to leave a trial at

any time—either before it starts or at any time during the trial or during the follow-up period. It is important for people who decide to leave a trial to get information from the research team about how to leave the trial safely.

The informed consent process continues throughout a trial. If new benefits, risks, or side effects are discovered during the course of a trial, the researchers must inform the participants so they can decide whether or not they want to continue to take part in the trial. In some cases, participants who want to continue to take part in a trial may be asked to sign a new informed consent form.

New interventions are often studied in a stepwise fashion, with each step representing a different "phase" in the clinical research process. The following phases are used for cancer treatment trials:

Phases of a Clinical Trial

Phase 0. These trials represent the earliest step in testing new treatments in humans. In a phase 0 trial, a very small dose of a chemical or biologic agent is given to a small number of people (approximately 10-15) to gather preliminary information about how the agent is processed by the body (pharmacokinetics) and how the agent affects the body (pharmacodynamics). Because the agents are given in such small amounts, no information is obtained about their safety or effectiveness in treating cancer. Phase 0 trials are also called micro-dosing studies, exploratory Investigational New Drug (IND) trials, or early phase I trials. The people who take part in these trials usually have advanced disease, and no known, effective treatment options are available to them.

Phase I (also called phase 1). These trials are conducted mainly to evaluate the safety of chemical or biologic agents or other types of interventions (e.g., a new radiation therapy technique). They help determine the maximum dose that can be given safely (also known as the maximum tolerated dose) and whether an intervention causes harmful side effects. Phase I trials enrol small numbers of people (20 or more) who have advanced cancer that cannot be treated effectively with standard (usual) treatments or for which no standard treatment exists. Although evaluating the effectiveness of interventions is not a primary goal of these trials, doctors do look for evidence that the interventions might be useful as treatments.

Phase II (also called phase 2). These trials test the effectiveness of interventions in people who have a specific type of cancer or related cancers. They also continue to look at the safety of interventions. Phase II trials usually enrol fewer than 100 people but may include as many as 300. The people who participate in phase II trials may or may not have been treated previously with standard therapy for their type of cancer. If a person has been treated previously, their eligibility to participate in a specific trial may depend on the type and amount of prior treatment they received. Although phase II trials can give some indication of whether or not an intervention works, they are almost never designed to show whether an intervention is better than standard therapy.

Phase III (also called phase 3). These trials compare the effectiveness of a new intervention, or new use of an existing intervention, with the current standard of care (usual treatment) for a particular type of cancer. Phase III trials also examine how the side effects of the new

intervention compare with those of the usual treatment. If the new intervention is more effective than the usual treatment and/or is easier to tolerate, it may become the new standard of care.

Phase III trials usually involve large groups of people (100 to several thousand), who are randomly assigned to one of two treatment groups, or "trial arms": (1) a control group, in which everyone in the group receives usual treatment for their type of cancer, or 2) an investigational or experimental group, in which everyone in the group receives the new intervention or new use of an existing intervention. The trial participants are assigned to their individual groups by random assignment, or randomisation. Randomisation helps ensure that the groups have similar characteristics. This balance is necessary so the researchers can have confidence that any differences they observe in how the two groups respond to the treatments they receive are due to the treatments and not to other differences between the groups.

Randomisation is usually done by a computer program to ensure that human choices do not influence the assignment to groups. The trial participants cannot request to be in a particular group, and the researchers cannot influence how people are assigned to the groups. Usually, neither the participants nor their doctors know what treatment the participants are receiving.

People who participate in phase III trials may or may not have been treated previously. If they have been treated previously, their eligibility to participate in a specific trial may depend on the type and the amount of prior treatment they received.
In most cases, an intervention will move into phase III testing only after it has shown promise in phase I and phase II trials.

Phase IV (also called phase 4). These trials further evaluate the effectiveness and long-term safety of drugs or other interventions. They usually take place after a drug or intervention has been approved by the medicine regulatory office for standard use. Several hundred to several thousand people may take part in a phase IV trial. These trials are also known as post-marketing surveillance trials. They are generally sponsored by drug companies.

Sometimes clinical trial phases may be combined (e.g., phase I/II or phase II/III trials) to minimize the risks to participants and/or to allow faster development of a new intervention.

Although treatment trials are always assigned a phase, other clinical trials (e.g., screening, prevention, diagnostic, and quality-of-life trials) may not be labelled this way.

Use of Placebos

The use of placebos as comparison or "control" interventions in cancer treatment trials is rare. If a placebo is used by itself, it is because no standard treatment exists. In this case, a trial would compare the effects of a new treatment with the effects of a placebo. More often, however, placebos are given along with a standard treatment. For example, a trial might compare the effects of a standard treatment plus a new treatment with the effects of the same standard treatment plus a placebo.

Possible benefits of taking part in a clinical trial

The benefits of participating in a clinical trial include the following:

- Trial participants have access to promising new interventions that are generally not available outside of a clinical trial.
- The intervention being studied may be more effective than standard therapy. If it is more effective, trial participants may be the first to benefit from it.
- Trial participants receive regular and careful medical attention from a research team that includes doctors, nurses, and other health professionals.
- The results of the trial may help other people who need cancer treatment in the future.
- Trial participants are helping scientists learn more about cancer (e.g., how it grows, how it acts, and what influences its growth and spread).

Potential harms associated with taking part in a clinical trial

The potential harms of participating in a clinical trial include the following:

- The new intervention being studied may not be better than standard therapy, or it may have harmful side effects that doctors do not expect or that are worse than those associated with standard therapy.
- Trial participants may be required to make more visits to the doctor than they would if they were not in a clinical trial and/or may need to travel farther for those visits.

Correlative research studies, and how they are related to clinical trials

In addition to answering questions about the effectiveness of new interventions, clinical trials provide the opportunity for additional research. These additional research studies, called correlative or ancillary studies, may use blood, tumour, or other tissue specimens (also known as 'biospecimens') obtained from trial participants before, during, or after treatment. For example, the molecular characteristics of tumour specimens collected during a trial might be analysed to see if there is a relationship between the presence of a certain gene mutation or the amount of a specific protein and how trial participants responded to the treatment they received. Information obtained from these types of studies could lead to more accurate predictions about how individual patients will respond to certain cancer treatments, improved ways of finding cancer earlier, new methods of identifying people who have an increased risk of cancer, and new approaches to try to prevent cancer.

Clinical trial participants must give their permission before biospecimens obtained from them can be used for research purposes.

When a clinical trial is over

After a clinical trial is completed, the researchers look carefully at the data collected during the trial to understand the meaning of the findings and to plan further research. After a phase I or phase II trial, the researchers decide whether or not to move on to the next phase or stop testing the intervention because it was not safe or effective. When a phase III trial is completed, the researchers analyse the data to determine whether the results have medical importance and, if so, whether the tested intervention could become the new standard of care.

The results of clinical trials are often published in peer-reviewed scientific journals. Peer review is a process by which cancer research experts not associated with a trial review the study report before it is published to make sure that the data are sound, the data analysis was performed correctly, and the conclusions are appropriate. If the results are particularly

important, they may be reported by the media and discussed at a scientific meeting and by patient advocacy groups before they are published in a journal. Once a new intervention has proven safe and effective in a clinical trial, it may become a new standard of care.
(National Cancer Institute).

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