

## Role of Relaxation Technique in Oncology Patients - A Review of Non RCT's Studies

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### **Abstract:**

Cancer is a disease which can have an effect on any of the body part, is second leading cause of deaths worldwide with the mortality on the higher side in the developing countries of the world. Breast Cancer in females and prostate cancer in the males are found to be more prevalent among that particular gender. Different treatment approaches to treat the cancer symptoms are available among which the effects of chemotherapy affects the cancer patients most significantly. Life expectancy of the patients has increase as a result of pharmacological drugs but they alone were not found to be effective. Other treatment approaches like relaxation therapy in form of progressive muscular relaxation, breathing exercise and guided imagery alone or in combination have shown to have positive effect on cancer symptoms. The need of this review article was to review the non RCT studies that are available in the literature. **Methodology:** Medical and psychological electronic literature databases, including Cochrane database, Pubmed, PEDro, SCIRE, EMBASE, CINAHL, Google Scholar, Science Direct, and Psych INFO were used for computer based search. Studies published till 2021 which meet the inclusion criteria like Studies which are Non RCT in nature, with participants above 18 years of age suffering from any cancer symptom, where relaxation alone or with other treatment was used, published in English language in between the year 2005 to 2021 only got included in the review. **Results:** 55 studies were recognized initially which after scrutinizing for the title and abstract of the article 30 studies were recognized. A thorough search for the inclusion criteria and removing the duplicate studies and studies having only abstract 11 article meeting the inclusion were included in this review **Conclusion:** Relaxation technique is found to be useful in decreasing the burden of cancer related symptoms with limitations. Future studies with good research construct and homogenous research characteristics can give better information about the long term effectiveness of relaxation therapy on cancer symptoms.

**Keywords:** Relaxation technique, Non Pharmacological Cancer treatment, Cancer, Cancer symptoms, Quality of life

Cancer is a disease which can have an effect on any of the body part, is second leading cause of deaths worldwide. <sup>1,2,3</sup> The mortality rate in developing countries are on higher side as cancer is diagnosed late in these countries. <sup>1,4</sup> It is widely spread among females as breast cancer, as globally affection rate is nearly 1.7 million new cases annually. <sup>5,6</sup> Breast cancer is 45.1% prevalent among all types of cancer in females. <sup>7</sup> Prostrate cancers found among males is the second leading cause of death with a steady rise. <sup>5,8</sup> Various treatment like Immunotherapy, chemotherapy, radiotherapy and surgical treatment are available to treat various kinds of Cancer. <sup>9</sup>

As a result of the above mentioned treatments for treating Cancer, there has been an increase in life expectancy of the cancer survival but the overall quality of life, daily activities and performance have found to be deteriorating as a result of side effects of cancer treatment. <sup>1,5</sup> Chemotherapy among other cancer treatment is found to give major side effects followed by radiation therapy as patients suffer from minor side effects like gastrointestinal upset to major one like reduced libido. <sup>3,4,10,11,12,13</sup> Cancer pain, fatigue, insomnia, emotional and psychological problems like stress, anxiety are main concern as these

symptoms are most commonly found in different types of cancer patients undergoing various cancer treatment. <sup>1, 3, 4, 7, 8, 9, 13, 14, 15, 16</sup>

To treat the cancer symptoms pharmacological treatment including antidepressant and anti anxiety drugs are gaining popularity but pharmacological treatment on its own cannot completely reduce the cancer symptoms. <sup>1, 11</sup> Physical exercise, Relaxation technique, Reiki therapy, meditation and cognitive behavioural therapy are effective in reducing cancer related symptoms burden. <sup>1, 14, 16, 17</sup> Progressive muscle relaxation is one of the effective non pharmacological treatment used as palliative treatment to reduce cancer symptoms. <sup>1, 6</sup> Muscle relaxation leads to decreased cortisol level and Tumor necrotizing factor alpha and Interleukin-6 as result of diminished neuroendocrine function and activation of sympathetic nerves. This in turn reduces physical and psychological stresses. It is simple technique which can be performed at any place for a minimum of 15 mins to get the desired effects with minimum side effects. <sup>6</sup> Relaxation techniques in form of diaphragmatic breathing have also shown to lessen the cancer symptoms. <sup>1, 4</sup>

In our previous review 1, all the Randomized controlled Trials (RCT) which found the use of Relaxation technique alone or in combination with other techniques in reducing cancer symptoms were considered. All studies other than RCT were not considered. During search for RCT studies there were many non RCT studies which provided vital information about relaxation therapy in the treatment of cancer symptoms were found and are considered in this review.

## Methodology:

### Inclusion Criteria:

Studies which are Non RCT in nature, with participants above 18 years age suffering from any cancer symptom, where relaxation alone or with other treatment was used. The study should be published in English language in between 2005 to 2021 only.

### Exclusion Criteria:

Studies got excluded if they were RCT or Systematic review or meta analysis. Non RCT studies with participants below 18 years suffering from cancer and where patients were suffering from other disease other than cancer.

### Selection of Studies

Medical and psychological electronic literature databases, including Cochrane database, Pubmed, PEDro, SCIRE, EMBASE, CINAHL, Google Scholar, Science Direct, and Psych INFO were used for computer based search. Studies published till 2021 which meet the inclusion criteria got included in the review. Key words used for electronic database search were Relaxation technique, Non Pharmacological Cancer treatment, Cancer, Cancer symptoms, Quality of life. 55 studies were recognized initially which after scrutinizing for the title and abstract of the article 30 studies were recognized. A thorough search for the inclusion criteria and removing the duplicate studies and studies having only abstract 11 article meeting the inclusion were included in this review as shown in figure 1.

### Data items and Collection

Details of the studies included along with their important features such as study design, sample size, length of the study, outcome measures and results are highlighted in the table 1.

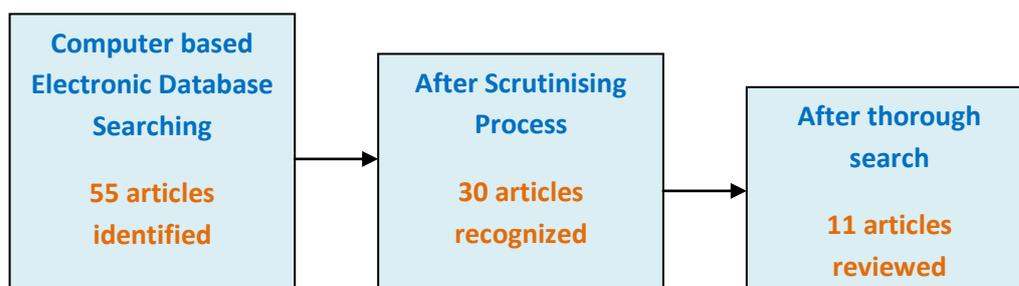


Figure 1: shows the Review process

Table 1: shows the details about the non RCT studies included in the review

Source of Article (Author/ Country/ & year	Study Design with Comparator	Participants/ Sample size/ Characteristics	Type of Cancer Patients	Type of intervention/ relaxation exercise	Length of Intervention	Variable/ Parameter and Outcomes	Findings
Kwekkeboom KL, US, 2008 <sup>(15)</sup>	pilot study with crossover design	N=40, age $\geq$ 18 years, 18 males and 22 females were included	Hospitalized patients with cancer pain	Each participant received two trials of a control condition, two trials of PMR, and two trials of analgesic imagery. The study was conducted over a two-day period, with subjects receiving one control trial and two trials of PMR or imagery on each day.	2 days	Cancer pain; Pain intensity and pain related distress were measured before and after each trial and perceived control over pain was measured after each trial.	Researchers and clinicians alike need to understand Individual difference variables that moderate effects of cognitive-behavioral strategies if we are to adequately test their efficacy and identify appropriate treatments for patients with cancer pain.
Demiralp M, Turkey, 2010 <sup>(14)</sup>	Prospective, repeated measures, quasi-experimental design with control group.	N=27 (14 in the Intervention group & 13 in the Control group (25- 65 years of age)	Patients who had been diagnosed with breast cancer and have planned to be treated with adjuvant chemotherapy	The effect of the PMRT was measured at different stages of the treatment. Each session of PMRT was approximately 25–30 minutes long. PMRT sessions were performed on the 1st and 15th day of each chemotherapy cycle. Thus, after four chemotherapy cycles, eight PMRT sessions had been performed in total.	3 Months	Sleep Quality and fatigue; data collection form, Pittsburgh Sleep Quality Index to evaluate sleep quality and Piper Fatigue Scale to measure fatigue in cancer patients were used to collect the data.	Progressive muscle relaxation training would improve sleep quality and fatigue in patients with breast cancer undergoing adjuvant chemotherapy.
Mohamad Rodi Isa et al., Malaysia, 2013 <sup>(8)</sup>	quasi-experimental study	N=193 Male subjects (109 patient in the intervention group and 84 patient in the comparison group) Age: 50 years and above.	patients diagnosed with prostate cancer	The intervention was the Applied Progressive Muscle Relaxation Training (APMRT) Program. It was a one hour therapy that consisted of six modules. A total of three session's one-hour therapy was conducted over six weeks. In addition to that, abdominal breathing technique was taught to enhance relaxation.	6 Months	The depression, anxiety and stress levels were assessed using self-reported Depression Anxiety Stress Scale - 21 (DASS-21)	There were no significant different in the improvement of depression score comparing both group. It can be concluded that APMRT has no advantage in the improvement of depression among prostate cancer patients.
Yilmaz SG et al., Turkey, 2015 <sup>(7)</sup>	Quasi-experiment with pre- and post-test design.	N =60 female subjects (30 in each experimental & Control group)	Turkish Breast Cancer patients	For the control group, routine nursing care and For the experimental group Progressive relaxation exercises training was performed	3 weeks	Anxiety and comfort level; State trait Anxiety inventory and general comfort Scale	Progressive relaxation exercise positively affect patient comfort and anxiety levels in Turkey

Nicolussi A C, Brazil, 2016 <sup>(13)</sup>	Quasi-experimental study	N=152 M=67 (28 in experimental & 39 in Control group) F=85 (45 in experimental & 40 in Control group) Age (≥18 years)	The most frequent cancers were breast, intestinal and gastric cancers etc who went for chemotherapy at interval of 21 days.	Relaxation therapy with guided imagery. 1st session was held on the first day of treatment and was monitored by the researcher with 6 years of experience in therapy. At the end of the session, copies of the CD with the exercises were given to the participants. They need to perform the exercises at home, at least 1 to 3 times a week during chemotherapy treatment.	6 Months	Depression; Beck Depression Inventory (BDI)	According to the BDI, there were statistically significant differences between the groups and the periods of time, and the IG had a greater number of patients “without depression” than the CG at the end of the study.
Paras-Bravo et al., Spain, 2017 <sup>(12)</sup>	Multi-centered pre-post interventional study without a control group.	N=272, Male=63 subjects and Female= 203 & 6 drop outs (18 years or older)	Patient with different Oncologic pathologies (oncological and/or hematological malignances)	The intervention comprised abbreviated progressive muscle relaxation training, according to Bernstein and Borkovec. This was followed by weekly telephone calls to each patient over a 1-month period.	1 Month	Patients' quality of life was assessed using the Functional Assessment of Cancer Therapy-General (FACT-G) questionnaire and an ad hoc data collection notebook.	Patients with cancer who learned and practiced abbreviated progressive muscle relaxation experienced improvement in their perceived quality of life as measured by the FACT-G.
Larios-Jimenez, et al. US, 2018 <sup>(4)</sup>	Experimental Study	N=552 (M=93 and F=459) (not clearly specified but more than 30 years of age)	Patients of the chemotherapy areas of three hospitals in the Metropolitan area of Guadalajara were included	Patient navigation program consisting of 40 to 60 minutes session of Guided Imagery technique along with the Relaxation therapy in form of Diaphragmatic Breathing Exercise	After chemotherapy	A Visual Analog Scale was designed to measure the level of tension, anxiety or stress the participant was feeling before and after the relaxation technique application.	The study results highlighted the effectiveness of relaxation techniques implemented in patients receiving chemotherapy, reducing perceived stress, anxiety and tension. Health professionals can train patients on the use of relaxation techniques during their hospital visits.
Kurt B., Kapucu S., Turkey, 2018 <sup>(9)</sup>	Non-randomized controlled, open-label, parallel group experimental design	n=49, intervention (n=25) and control (n=24), ages of 18 and 65	Breast cancer undergoing adjuvant chemotherapy.	The intervention group received instruction in relaxation exercises from the researcher in the clinic. They practiced in the hospital with the researcher in the clinic, and individually applied the exercises at home. The patients in the control group received only standard medical care.	74 days	Edmonton Symptom Diagnostic Scale (ESDS) is an analog scale used to assess the severity of nine common chemotherapy symptoms (pain, fatigue, nausea, sadness, anxiety, sleeplessness, anorexia, feeling bed, drowsiness and other problems)	Relaxation exercises had a positive effect on decreasing the symptoms resulting from adjuvant chemotherapy. Thus, the use of relaxation exercises may be recommended for reducing the severity of chemotherapy Symptom's in patients with breast cancer receiving adjuvant chemotherapy.
Mulhaeri ah et al.,	Quasi-experiment	N=42 female subjects (21	Gynaecological cancer patients	21 of subjects were assigned to the group receiving RBE four times a day and	7 days	Fatigue; Piper Fatigue Scale	Conducting RBE four times a day effectively alleviated fatigue better

Indonesia, 2018 <sup>(16)</sup>	with pre- and post-test design.	subjects in each group)	undergoing chemotherapy.	whereas other 21 were assigned to the group receiving RBE twice a day.			than RBE twice a day on gynaecological cancer patients undergoing chemotherapy.
N. Vuttanon et al., Thailand, 2019 <sup>(6)</sup>	Quasi-experimental trial was designed with pre- and post-test control.	N=96 female subjects(48 in each group), older than 20 years	Breast cancer patient receiving chemotherapy	Participants in the experimental group first received PMR training at the hospital where the entire PMR process was demonstrated and explained from a CD developed by the researchers. In control group, participants received routine care, including home medications such as: antiemetic and pain relief drugs, and discharge advice following chemotherapy.	7 days after discharge	Cluster of cancer symptoms; Edmonton Symptom Assessment Scale (ESAS).	PMR might be a useful nursing intervention to alleviate symptoms in breast cancer patients undergoing chemotherapy. Further studies are needed to verify the effect of PMR in reducing symptom clusters.
Bhatia M et. al, India, 2020 <sup>(3)</sup>	Quasi experimental with pre-test post-test control group design	N=40 (20 patients each in experimental and comparison group), (total M=19 and F=21) age group ≥ 18 years.	Gastro Intestinal Cancer Patients receiving chemotherapy	Experimental group patients were administered with Progressive Muscle relaxation therapy (PMRT) while the comparison group patients received routine care as per the hospital protocol	3 weeks	Universal Pain Assessment Tool:Pain; Insomnia Severity Index Scale : Insomnia; Common Toxicity Criteria for Adverse Events Version-5 : Fatigue, Nausea/ Vomiting and Anorexia; and Karnofsky Performance Status Scale : Performance status.	PMRT is effective in decreasing the physical symptoms of insomnia and fatigue in cancer patients receiving chemotherapy admitted in cancer Institute.

Table 2 Showing the Quality of the non RCT studies included in the review

Non Randomized Controlled trials			Non Randomized Controlled trials		
Source of Article (Author/ Country/ & year	Score as for the Non clinical trials (18) (Out of 100)	Quality of the Study	Source of Article (Author/ Country/ & year	Score as for the Non clinical trials (18) (Out of 100)	Quality of the Study
Kwekkeboom KL, US, 2008 <sup>(15)</sup>	95	Good	Larios-Jimenez, et al. US, 2018 <sup>(4)</sup>	90	Good
Demiralp M, Turkey, 2010 <sup>(14)</sup>	90	Good	B. Kurt, S. Kapucu, Turkey, 2018 <sup>(9)</sup>	90	Good
Mohamad Rodi Isa et al., Malaysia, 2013 <sup>(8)</sup>	80	Good	Mulhaeriah et al., Indonesia, 2018 <sup>(16)</sup>	80	Good
Yilmaz SG et al., Turkey, 2015 <sup>(7)</sup>	90	Good	N. Vuttanon, et al., Thailand, 2019 <sup>(6)</sup>	80	Good
Nicolussi A C, Brazil, 2016 <sup>(13)</sup>	80	Good	Bhatia M et. al, India, 2020 <sup>(3)</sup>	80	Good
Paras-Bravo et al., Spain, 2017 <sup>(12)</sup>	80	Good			

## Results

### Study Characteristics

In current narrative review, a total of 11 non RCT studies meeting the inclusion criteria published from different corners of the world got reviewed. No homogeneity was found among the articles. Out of the 11 Non Randomized control trial seven studies were Quasi-experimental Studies, two pilot studies including one cross over trial and two experimental studies in which one was open label, parallel group design. Level of evidences of the non RCT studies was lesser than II with reference to the pyramid of level of evidences. Out of the 11 Non RCT studies all the studies were good in nature as per the scoring system. (Refer table no. 2)

### Sample Characteristics

Non randomized trial groups had patients suffering from various kinds of cancer like breast cancer, prostate cancer patient undergoing radiotherapy, gynaecological cancer such as ovarian carcinoma and cervical carcinoma, hospitalized patients with cancer pain, intestinal and gastric cancers, oncological and/or hematologic malignancies. Out of 11 studies, 5 non randomised studies included breast cancer patients as the Cancer population pointing out to the fact about prevalent occurrence of breast cancer. Similar finding was got when review was done for the RCT studies. <sup>1</sup>

Few of the studies did not clearly specific the age criteria but majority of the subjects included were between 18 to 65 years of age. 4 studies had sample size  $\geq 100$ .

### **Intervention Characteristics**

Different types of relaxation training (interventions) were given to the patients in different studies with relaxation technique being given alone 6 studies while for the rest of the studies relaxation technique was compared with or given in combination with the other techniques like analgesic imagery, guided imagery with Breathing exercise, routine nursing care, usual/ routine care. (Refer table No. 1)

### **Outcome Characteristics**

Different types of Outcome measures were used for different parameters like anxiety, depression, pain, sleep, tension, quality of life and other symptoms like nausea/ vomiting, anorexia. No homogeneity was found among the different studies related to any of the specific outcome measures used.

### **Discussion**

In the previous article,<sup>1</sup> where only the RCT studies were reviewed, the effect of relaxation therapy alone or in combination with other treatment techniques have been discussed in detail. In this article, an attempt has been made to understand the effect of relaxation therapy on different types of cancer patient in relieving different kinds of cancer symptoms using the non RCT studies.

Cancer patients frequently experience physical and psychological stress as a result of their illness and treatment side effects. The sympathetic nervous system raises catecholamine, nor-epinephrine, and epinephrine levels in response to stress. Concurrently, the hypothalamic-pituitary-adrenal axis stimulates the release of pro-inflammatory cytokines and cortisol, which causes the muscles in the body to tense up. Through deep muscular relaxation and mind-body awareness, PMR may lessen the ensuing physical strain and lower stress hormones.<sup>19</sup> In addition to reducing physical discomfort and exhaustion, the ensuing synthesis of endorphin, enkephalin, and serotonin may also improve sleep quality.<sup>6</sup> The findings support the growing part of research demonstrating that PMR is a methodical approach that can be utilized to attain a profound level of relaxation.<sup>6,20</sup> It is beneficial for both mental and physical wellness.<sup>6</sup>

Kwekkeboom et al. in their article described that for several participants, the PMR and analgesic imagery therapies seemed beneficial. The group averages indicated that compared to the control condition, both cognitive-behavioral techniques were considerably more effective in improving pain outcomes. These results align with those of other researchers who found that hospitalized cancer pain patients benefited from PMR and imagery therapies.<sup>15, 21, 22, 23</sup> More than three-quarters of participants informed the author that they appreciated and considered PMR to be useful after the intervention trials were over. More over half said they thought the analgesic imagery intervention was beneficial and enjoyable.<sup>15</sup>

Yilmaz et al in their study showed that the 0.91 difference in mean between the two groups indicated that the RBE is more effective in reducing fatigue in the group that received it four times a day than in the group that conducted it only twice a day for seven days. Thus, the researchers came to the conclusion that patients receiving chemotherapy for gynecological cancer experience a significant reduction in fatigue when treated with four times as much RBE.<sup>16</sup> Devi also noted that during external radiation therapy, cancer patients' degree of fatigue was decreased by deep breathing exercises that were programmed.<sup>16, 24</sup> The 0.91 difference in mean between the two groups showed that the RBE is more effective in reducing fatigue in the group that received it four times a day than in the group that conducted it only twice a day for seven days.<sup>16</sup>

Mishra et al. (2012) examined the impact of exercise intervention on quality of life in all cancer patients undergoing chemotherapy. They discovered that the exercise regimen was most successful in the group of patients with breast cancer, who also experienced improved physical functioning and decreased levels of fatigue, depression, and sleeping disorders.<sup>7, 25</sup>

In a study involving patients with prostate cancer, Isa et al. (2013)<sup>7, 20</sup> discovered that the patients' quality of life was enhanced by the progressive relaxation exercises. According to a 2012 study by Hayama and Inoue, patients with gynecological cancer receiving adjuvant chemotherapy reported feeling less anxious and fatigued after engaging in deep breathing exercises. On searching the literature studies that demonstrate how chemotherapy side effects have decreased, resulting in increased comfort. According to Kolcaba's definition, the authors came to the conclusion that these procedures provide patients with a certain amount of comfort and enhance their quality of life.<sup>7</sup>

Regular exercise under expert supervision lowers fatigue by assisting the body in utilizing its energy.<sup>9, 26</sup> The literature<sup>9, 27</sup> examined the relationship between PRE and fatigue and discovered a significant decrease in fatigue severity in the Intervention Group. Patients in the study used PRE under the investigator's supervision for 74 days. Prescription energy use may have an impact on fatigue. In randomized controlled trials, PRE decreased the frequency and duration of nausea and vomiting (RCTs)<sup>9, 28</sup> The research on the implementation of PRE showed significant reduction of anxiety and depression severity in the Intervention Group as per the literature.<sup>9, 29, 30, 31</sup>

Patients experience a decrease in sleeplessness feeling as a result of PRE because it refocuses their attention in a different area, improving their comfort and well-being.<sup>9, 30</sup> PRE has been used to treat cancer patients' insomnia as well as their sleeping habits. In the Intervention Group, there was a decrease in the frequency of night time awakenings and an increase in sleep latency, duration, and quality. PRE, especially when done right before bed, may help to calm the body as it goes to sleep.<sup>9, 27, 28, 32, 33</sup> The progressive relaxation technique, which reduces tension of most of the muscles, greatly minimizes sleep disturbances.<sup>9</sup>

The ability of relaxation therapy to lower anxiety levels may stem from the stimulation of parasympathetic activity, which lowers blood pressure, heart rate, muscle tension, breathing rate, and induces feelings of calmness and control.<sup>8, 34</sup> Additionally, Sharpley et al. (2007) discovered a correlation between a decrease in psychomotor, agitation, weakness, and pessimism and a decreased anxiety level.<sup>8, 35</sup>

In a study on comparison to the control group, the PMR group felt more rested, better able to carry out daily tasks, and experienced no negative effects on their cognitive abilities. In their eight-week study on cancer survivors,<sup>14, 36</sup> Davidson et al. (2001) report a significant improvement in fatigue and sleep scores in the non-pharmacological treatment group that included relaxation exercises. Adamsen et al. (2004) found that using the multidimensional exercise program they created, cancer patients' fatigue symptoms improved after six weeks.<sup>14, 37</sup> In their study of patients who had received bone marrow transplants, Kim and Kim (2005) discovered that six weeks of relaxation exercises significantly reduced the perceived fatigue subcomponents.<sup>14, 38</sup>

### **Strength of the study:**

**SANRA scale**<sup>39</sup> modified in 2014 for the analysis of quality of narrative review was kept in the mind while writing this narrative review. This scale has six items which assess the construct of the narrative review to improve the quality of the published reviews.

### **Limitations of the Study**

The major limitation of the study was that no RCT studies were taken into consideration during this review as already review considering RCT studies have been published by the author. The heterogeneity in the treatment approach and the outcome measures used with different treatment duration makes it a difficult task in the review process.

### **Future research**

Further long term studies with large sample size and good research design construct is the need of the hour so that the effect of relaxation therapy alone or in combination with other therapy can be effectively reviewed.

### **Conclusions**

Relaxation technique in the form of progressive muscle relaxation technique, deep breathing exercise and or guided imagery is found to be useful in decreasing the burden of cancer related symptoms with limitations. Future studies with good research construct and homogenous research characteristics can give better information about the effectiveness of relaxation therapy on different types of cancer symptoms.

### **Conflicts of Interest**

The author hereby states that he have no potential conflicts of interest to declare.

### **Funding**

This research received no particular grants from any funding agency in either, the public, commercial or not-for-profit sector.

### **Ethical Approval**

Not applicable, because this article does not contain any studies in which the need to recruit any human or animal subjects arises.

### **Informed Consent**

Not applicable, because this article does not contain any studies with human or animal subjects.

### **Trial Registration**

Not applicable, because this article does not contain any clinical trials.

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