

# The massage in children with cancer: Effectiveness of a protocol

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
18/12/2012	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
10/01/2013	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
10/01/2013	Cancer	<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Pain is an unpleasant and subjective experience that has sensorial, affective, cognitive, social and behavioral components. It is a major cause of human suffering and loss of quality of life. Health professionals have an ethical responsibility and a key role to play in order to provide effective pain control.

Unconventional therapies exist but there is little evidence about well they work. This is the case for children with cancer. The aim of this study is to evaluate how well three massage sessions will work in reducing pain in children with cancer aged between 10 and 18 years old.

### Who can participate?

Children diagnosed with cancer and undergoing treatment (chemotherapy, antibiotics, or steroids). It excluded children not diagnosed, in terminal phase, in the first three days after surgery, in isolation from contact, with fever, bleeding risk and altered states of consciousness or cognitive disturbances.

### What does the study involve?

Participants were randomly allocated to a treatment group or a control group. In the treatment group, the treatment consisted in three massage sessions on alternate days during a week (day 1, 3 and 5). The massage technique included gliding movements, light compression and the use of heated sweet almond oil. Each session lasted between 20 and 30 minutes. The control group received usual care. All children received the same care, except the application of massage in the treatment group.

### What are the possible benefits and risks of participating?

Study participants could benefit from better pain control and less interference of pain in their daily lives. There are no risks as long as the exclusion criteria are followed.

The study was conducted according to the Declaration of Helsinki of the World Medical Association. Written consent was provided by the child and the child's legal guardians.

### Where is the study run from?

This study involved the Nursing School of Coimbra and Portuguese Oncology Institute of Porto (Portugal).

When is the study starting and how long is it expected to run for?  
The study took place at the Portuguese Oncology Institute of Porto between November 2010 and March 2011.

Who is funding the study?  
Portuguese Oncology Institute of Porto (Portugal)

Who is the main contact?  
Professor Luís Batalha  
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## Contact information

### Type(s)

Scientific

### Contact name

Prof Luís Batalha

### Contact details

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## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

The massage in children with cancer: Effectiveness of a protocol a randomized controlled trial

### Study objectives

The implementation of a protocol of three massage sessions on alternative days during a week reduces the pain and its interference in the activities of children (10 to 18 years), hospitalized with cancer.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics Committee for Health IPO-Porto (Comissão de Ética para a Saúde IPO-Porto), Portugal, 30 /09/2010, ref: 258/010

**Study design**

Single-center randomized controlled trial

**Primary study design**

Interventional

**Study type(s)**

Quality of life

**Health condition(s) or problem(s) studied**

Relief of pain in children with cancer through massage

**Interventions**

Children and adolescents hospitalized in a pediatric oncology department aged 10 to 18 years with a diagnostic disease and treatment (chemotherapy, antibiotics or steroids) were randomly divided into two groups (control and intervention).

The children in the intervention group (GI) were subjected to a protocol consisting of three massage sessions in alternative days, during a week (day 1, 3 and 5). The massage technique consisted of gliding movements, light compression and the use of heated sweet almond oil. Each session lasted between twenty and thirty minutes.

Control group (CG) received usual care.

Finally, the efficacy of the protocol was measured by analyzing the differences between the results at the beginning (day 0) and the results at the end of protocol (day 6) by evaluating the pain and their interference in the activities of children.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

The pain is measured by using the Visual Analogue Scale (VAS), scored (0 = no pain, 10 = unbearable pain) and physical functioning, assessed by the Brief Pain Inventory scales (BPI), scored numerical rating scale (0 = without interferences in the activity, 10 = the maxim interference) at the beginning (day 0) and at the end of protocol (day 6).

**Key secondary outcome(s)**

Pain intensity by the Visual Analogue Scale (VAS) scored (0 = no pain, 10 = unbearable pain) was assessed in a break of half-hour at the beginning and the end of each session massage.

**Completion date**

30/03/2011

**Eligibility****Key inclusion criteria**

Children between 10 and 18 years old hospitalized in a pediatric department with a diagnostic with cancer and treatment (chemotherapy, antibiotics or steroids)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Child

### **Lower age limit**

10 years

### **Upper age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Children in terminal phase
2. The first three days after surgery
3. In isolation from contact with fever
4. Bleeding risk (platelet count less than 10 000)
5. Altered states of consciousness or cognitive disorders

### **Date of first enrolment**

01/11/2010

### **Date of final enrolment**

30/03/2011

## **Locations**

### **Countries of recruitment**

Portugal

### **Study participating centre**

Escola Superior de Enfermagem de Coimbra

Coimbra

Portugal

3046-851

## **Sponsor information**

## Organisation

Nursing School of Coimbra (Escola Superior de Enfermagem de Coimbra) (Portugal)

## ROR

<https://ror.org/03c3y8w73>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Portuguese Oncology Institute of Porto [Instituto Português de Oncologia do Porto, Francisco Gentil, EPE (IPOPFG, E.P.E.)] (Portugal)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes