

The massage in children with cancer: Effectiveness of a protocol

Submission date 18/12/2012	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 10/01/2013	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 10/01/2013	Condition category Cancer	☐ Individual participant data ☐ 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

batalha@esenfc.pt

Contact information

Type(s)

Scientific

Contact name

Prof Luís Batalha

Contact details

Escola Superior de Enfermagem de Coimbra

Av. Bissaya Barreto Ap. 7001

Coimbra

Portugal

3046-851

+351 239 487 200

batalha@esenfc.pt

Additional identifiers

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

Primary study design

Interventional

Study design

Single-center randomized controlled trial

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 maximum 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