

# EVIDENCIA CIENTÍFICA EN FISIOTERAPIA (I)

Prof. Manuel Arroyo Morales

# CALIDAD DE LA INVESTIGACIÓN

Declaración CONSORT

Normas consolidadas para la  
publicación de Ensayos Clínicos

**Tabla 1.** Lista de comprobación de la Declaración CONSORT para ensayos controlados y aleatorizados

NÚMERO	SECCIÓN Y TEMA	DESCRIPCIÓN
1	Título y resumen	Cómo se asignan los participantes a las intervenciones
2	Introducción (antecedentes)	Antecedentes científicos, explicación y razonamiento
3	Métodos (participantes)	Criterios de elección de los participantes
4	Métodos (intervenciones)	Detalles de las intervenciones en cada grupo; cómo y cuándo
5	Métodos (objetivos)	Especificar objetivos y/o hipótesis
6	Métodos (resultados)	Definir medidas primarias y secundarias; cómo se incrementó la calidad de las mediciones
7	Métodos (tamaño de muestra)	Determinación del tamaño de la muestra
8	Métodos (aleatorización)	Método para generar secuencia aleatoria
9	Método (distribución a ciegas)	Método generado para implementar la secuencia aleatoria
10	Método (implementación)	Quién generó la secuencia de asignación, quién enroló a los participantes, quién los asignó a los grupos
11	Método (enmascaramiento)	Cómo se efectuó el enmascaramiento; cómo se evaluó éste
12	Métodos (estadística)	Métodos estadísticos usados para comparar grupos, análisis de subgrupos, etc.
13	Resultados (flujo de participantes)	Número de individuos en cada momento (diagrama de flujo); descripción de desviaciones
14	Resultados (reclutamiento)	Fechas de reclutamiento y seguimiento
15	Resultados (datos basales)	Datos demográficos de base y características clínicas de cada grupo
16	Resultados (números analizados)	N.º de participantes en cada grupo; indicación de análisis «por intención de tratar»
17	Resultados (estimación)	Resumen de resultados primario y secundario de cada grupo; precisión de los resultados
18	Resultados (análisis auxiliar)	Otros análisis (subgrupos, ajustados, etc.)
19	Resultados (eventos adversos)	Efectos adversos importantes observados en cada grupo
20	Comentarios (interpretación)	Interpretación en función de hipótesis, sesgos, etc.
21	Comentarios (generalizabilidad)	Validez externa de los resultados
22	Comentarios (evidencia global)	Interpretación global de resultados en función de la evidencia actual

# 1 Titulo y Resumen

## Como se asignan los participantes a las intervenciones

The image shows a screenshot of a web browser displaying a scientific article. The browser's address bar shows the URL: <http://download.springer.com/static/pdf/650/art%253A10.1007%252Fs00520-012-1549-x.pdf?auth66-13>. The article title is "Water versus land-based multimodal exercise program effects on body composition in breast cancer survivors: a controlled clinical trial", with "on body composition" circled in red. The authors listed are Carolina Fernández-Lao, Irene Cantarero-Villanueva, Angelica Ariza-García, Carol Courtney, César Fernández-de-las-Peñas, and Manuel Arroyo-Morales. The article was received on 12 March 2012 and accepted on 23 July 2012. The abstract states: "Goals of work Our aim was to compare the effects of land versus water multimodal exercise programs on body composition and breast cancer-specific quality of life in breast cancer survivors. Patients and methods Ninety-eight breast cancer survivors were assigned to three groups: control, land exercise, and water exercise. Both exercise groups participated in an 8-week multimodal program. Adiposity was measured by anthropometry (body mass index, waist circumference) and bioelectrical impedance (body fat and muscle lean body mass). Incidence of clinically significant secondary lymphedema was also assessed. Finally, specific quality of life was assessed using the European Organization for Research and Treatment of Cancer Quality of Life BR-23." The main results section states: "Main Results Using ANCOVA, significant group × time interactions for body fat percentage ( $F=3.376$ ;  $P=0.011$ ) and lean body mass ( $F=3.566$ ;  $P=0.008$ ) were found. Breast cancer survivors in the land exercise group exhibited a greater decrease in percentage of body fat than those in the water exercise ( $P<0.001$ ) and control ( $P=0.002$ ) groups. The ANCOVA revealed a significant group × time interaction for waist circumference ( $F=4.553$ ;  $P=0.002$ ); breast cancer survivors in the control group showed a greater waist circumference when compared to water ( $P=0.003$ ) and land ( $P<0.001$ ) exercise groups. A significant group × time interaction was also found for breast symptoms ( $F=9.048$ ;  $P<0.001$ ); participants in the water exercise group experienced a greater decrease of breast symptoms than those in the land exercise ( $P<0.01$ ) and control ( $P<0.05$ ) groups. Conclusion Land exercise produced a greater decrease in body fat and an increase in lean body mass, whereas water exercise was better for improving breast symptoms." The keywords are "Breast cancer; Exercise; Body composition".

## 2 Introducción

# Antecedentes científicos, explicación y razonamiento

The screenshot shows a Windows Internet Explorer browser window displaying a scientific article. The address bar shows the URL: <http://download.springer.com/static/pdf/650/art%253A10.1007%252Fs00520-012-1549-x.pdf?auth66-13>. The article title is "Water versus land-based multimodal exercise program effects on body composition in breast cancer survivors: a controlled clinical trial", with "on body composition" circled in red. The authors listed are Carolina Fernández-Lao, Irene Cantarero-Villanueva, Angelica Ariza-García, Carol Courtney, César Fernández-de-las-Peñas, and Manuel Arroyo-Morales. The article was received on 12 March 2012 and accepted on 23 July 2012. The abstract states the aim was to compare the effects of land versus water multimodal exercise programs on body composition and breast cancer-specific quality of life in breast cancer survivors. The main results indicate that land exercise produced a greater decrease in body fat and an increase in lean body mass compared to water exercise. The conclusion states that land exercise was better for improving breast symptoms.

ORIGINAL ARTICLE

### Water versus land-based multimodal exercise program effects on body composition in breast cancer survivors: a controlled clinical trial

Carolina Fernández-Lao · Irene Cantarero-Villanueva · Angelica Ariza-García · Carol Courtney · César Fernández-de-las-Peñas · Manuel Arroyo-Morales

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**Abstract**  
*Goals of work* Our aim was to compare the effects of land versus water multimodal exercise programs on body composition and breast cancer-specific quality of life in breast cancer survivors.  
*Patients and methods* Ninety-eight breast cancer survivors were assigned to three groups: control, land exercise, and water exercise. Both exercise groups participated in an 8-week multimodal program. Adiposity was measured by anthropometry (body mass index, waist circumference) and bioelectrical impedance (body fat and muscle lean body mass). Incidence of clinically significant secondary lymphedema was also assessed. Finally, specific quality of life was assessed using the European Organization for Research and Treatment of Cancer Quality of Life BR-23.

**Main Results** Using ANCOVA, significant group × time interactions for body fat percentage ( $F=3.376$ ;  $P=0.011$ ) and lean body mass ( $F=3.566$ ;  $P=0.008$ ) were found. Breast cancer survivors in the land exercise group exhibited a greater decrease in percentage of body fat than those in the water exercise ( $P<0.001$ ) and control ( $P=0.002$ ) groups. The ANCOVA revealed a significant group × time interaction for waist circumference ( $F=4.553$ ;  $P=0.002$ ); breast cancer survivors in the control group showed a greater waist circumference when compared to water ( $P=0.003$ ) and land ( $P<0.001$ ) exercise groups. A significant group × time interaction was also found for breast symptoms ( $F=9.048$ ;  $P<0.001$ ); participants in the water exercise group experienced a greater decrease of breast symptoms than those in the land exercise ( $P<0.01$ ) and control ( $P<0.05$ ) groups.

**Conclusion** Land exercise produced a greater decrease in body fat and an increase in lean body mass, whereas water exercise was better for improving breast symptoms.

**Keywords** Breast cancer · Exercise · Body composition

# 3 Métodos (Participantes)

## Criterios de elección de participantes

associated with significant reduction in body mass index and body weight in patients who have completed treatment for breast cancer [13, 36]. However, there is not clear evidence on which type of exercise modality is more feasible and efficient for improving body composition in breast cancer survivors.

Subgroups of breast cancer survivors have demonstrated improvements in various cancer-related symptoms such as reduced shoulder–neck mobility [31], shoulder–neck pain [12], and fatigue [9]. These cancer-related symptoms are intricately associated with functional limitations such as decreased levels of physical activity and weight gain [46]. Preliminary evidence supports the objective of maintaining high pre-diagnosis physical activity levels and a healthy body for better quality of life after breast cancer [45]. Therefore, studies investigating the most appropriate exercise programs which improve body composition and quality of life in breast cancer survivors are necessary.

Various studies have investigated the effects of different exercise modalities on body composition in breast cancer survivors during their rehabilitation phase. Exercise interventions including 150–225/min of moderate-to-vigorous aerobic exercise per week [18] or weight training [32] have been shown to improve body composition. In contrast, no significant changes in body composition have been observed after unsupervised light to moderate aerobic exercise interventions [26], resistance exercise [12], or mixed

### Methods and procedures

#### Participants

Breast cancer survivors recruited from the Breast Oncology Unit Hospital Virgen de las Nieves (Granada, Spain) from December 2009 to June 2011 gave their written informed consent prior to participation in the study. Participants were eligible if they (a) had a diagnosis of breast cancer (stage I–III A); (b) were between 25–65 years of age; (c) had finished co-adjuvant treatment except hormone therapy; (d) did not have active cancer; and (e) had four to five of the following physical findings, judged by the referring oncologist: neck or shoulder pain symptoms, reduced range of motion in neck–shoulder, reduced physical capacity, increased fatigue, sleep disturbances, or any problem in coping with reduced physical–psychosocial functioning. Participants were excluded if they (a) were receiving chemotherapy or radiotherapy treatment at the time of the study; (b) had chronic or orthopedic disease which did not permit them to follow the physical program; or (c) had uncontrolled hypertension (diastolic pressure > 95 mm Hg).

#### Study design

The sample size was calculated on an 80 % power to detect a mean difference of 0.7 kg [17] with a standard deviation similar

# 4 Métodos Intervenciones

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Support Care Cancer

**Table 1** Description of exercise programs

		Water group		Land group
Week 1–4		Materials	Pool noodles and swimming belt	Small soft ball, mats and fit-ball
<i>Main goal:</i> improving overall fitness	10 min	Warm-up	Aerobic games, mobility and stretching exercises	Aerobic games, mobility and stretching exercises
	30–40 min	Aerobic exercise	Unspecific work during sessions	Unspecific work during sessions
		Strength exercise	Exercise program to develop strength using water resistance.	Exercise program to develop strength without weight.
10 min	Cool-down	Medium velocity execution exercises and increase range of joint motion	Medium velocity execution exercises and increase range of joint motion	
Week 5–8		Materials	Pool noodles, pull buoy, swimming board	Fit-ball, elastic band, mats, and small soft ball
<i>Main goal:</i> specific training for improve aerobic, mobility and endurance conditions	10 min	Warm-up	Aerobic games, mobility and stretching exercises	Aerobic games, mobility, and stretching exercises
	30–40 min	Aerobic exercise	5–10 min of slow aerobic exercise (aqua running or swim)	10–25 min of fast working with arms movement two days per week
		Strength exercise	Exercise program to develop strength. Increase resistance with different materials and positions that require more body control.	Exercise program to develop strength. Increase resistance with different materials and positions that require more body control
10 min	Cool-down	Stretching, mobility and massage in pairs	Stretching, mobility, and massage in pairs	

Hecho

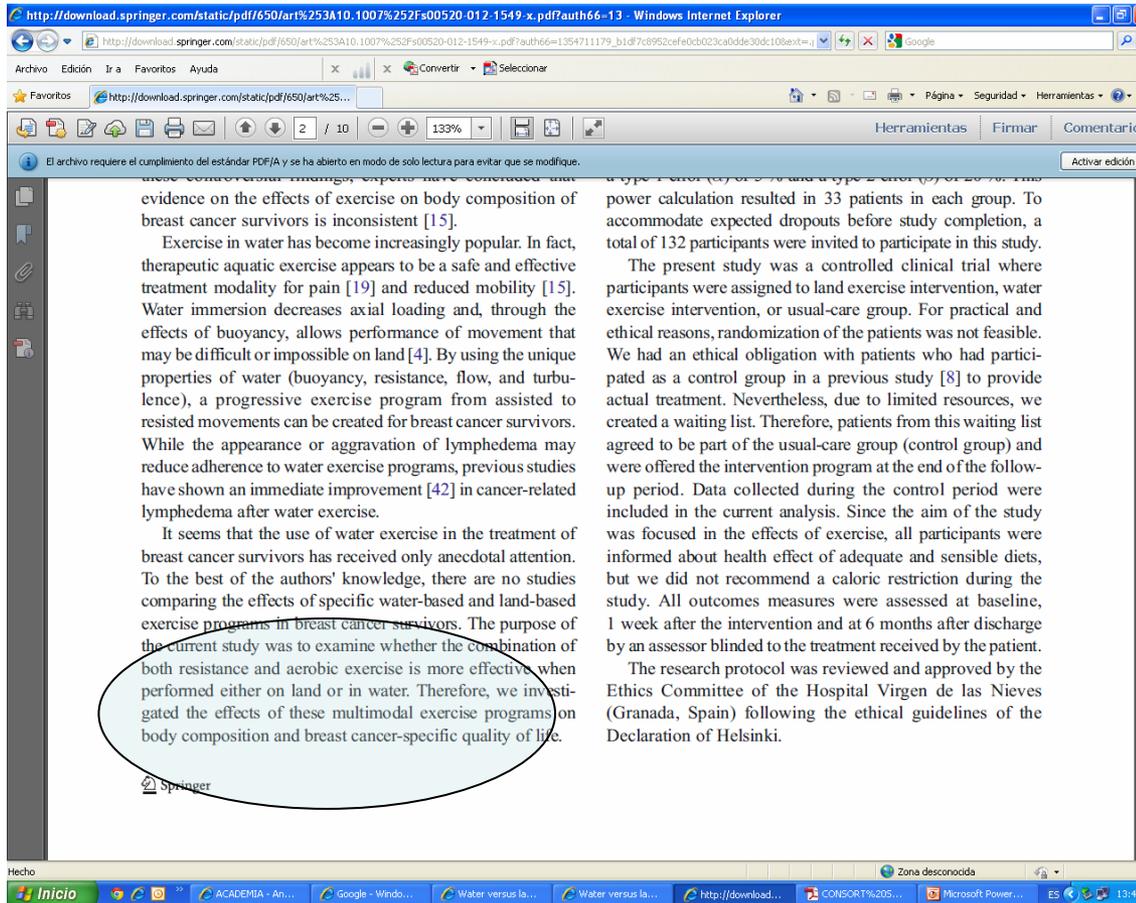
Zona desconocida

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**Precisar detalles de la intervención para cada grupo, y también precisar cuándo y Cómo fueron administrado**

# 5 Objetivos

## Especificar los objetivos y la hipótesis



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Exercise in water has become increasingly popular. In fact, therapeutic aquatic exercise appears to be a safe and effective treatment modality for pain [19] and reduced mobility [15]. Water immersion decreases axial loading and, through the effects of buoyancy, allows performance of movement that may be difficult or impossible on land [4]. By using the unique properties of water (buoyancy, resistance, flow, and turbulence), a progressive exercise program from assisted to resisted movements can be created for breast cancer survivors. While the appearance or aggravation of lymphedema may reduce adherence to water exercise programs, previous studies have shown an immediate improvement [42] in cancer-related lymphedema after water exercise.

It seems that the use of water exercise in the treatment of breast cancer survivors has received only anecdotal attention. To the best of the authors' knowledge, there are no studies comparing the effects of specific water-based and land-based exercise programs in breast cancer survivors. The purpose of the current study was to examine whether the combination of both resistance and aerobic exercise is more effective when performed either on land or in water. Therefore, we investigated the effects of these multimodal exercise programs on body composition and breast cancer-specific quality of life.

power calculation resulted in 33 patients in each group. To accommodate expected dropouts before study completion, a total of 132 participants were invited to participate in this study.

The present study was a controlled clinical trial where participants were assigned to land exercise intervention, water exercise intervention, or usual-care group. For practical and ethical reasons, randomization of the patients was not feasible. We had an ethical obligation with patients who had participated as a control group in a previous study [8] to provide actual treatment. Nevertheless, due to limited resources, we created a waiting list. Therefore, patients from this waiting list agreed to be part of the usual-care group (control group) and were offered the intervention program at the end of the follow-up period. Data collected during the control period were included in the current analysis. Since the aim of the study was focused in the effects of exercise, all participants were informed about health effect of adequate and sensible diets, but we did not recommend a caloric restriction during the study. All outcomes measures were assessed at baseline, 1 week after the intervention and at 6 months after discharge by an assessor blinded to the treatment received by the patient.

The research protocol was reviewed and approved by the Ethics Committee of the Hospital Virgen de las Nieves (Granada, Spain) following the ethical guidelines of the Declaration of Helsinki.

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## 6 Resultados

**Definir claramente las medidas primarias**

**Definir medidas secundarias**

**Definir métodos para incrementar calidad mediciones**

The diagram consists of three main elements arranged vertically. At the top is a light blue oval containing the text 'Variable Principal'. Below this is a horizontal orange bar containing the text 'Variables Secundarias'. At the bottom is a larger light blue oval containing the text 'Fiabilidad mediciones Intra / Inter examinador'. The elements are connected by thin lines, suggesting a flow or relationship from the primary variable down to the secondary variables and then to the measurement reliability.

Variable Principal

Variables Secundarias

Fiabilidad mediciones  
Intra / Inter examinador

# 7 Tamaño de la muestra

## Como fue determinado tamaño muestral

### Explicación análisis intermedio

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associated with significant reduction in body mass index and body weight in patients who have completed treatment for cancer [13, 36]. However, there is not clear evidence on which type of exercise modality is more feasible and efficient for improving body composition in breast cancer survivors.

Subgroups of breast cancer survivors have demonstrated various cancer-related symptoms such as reduced shoulder-neck mobility [31], shoulder-neck pain [12], and fatigue [9]. These cancer-related symptoms are intricately associated [12] causing functional limitations such as decreased levels of physical activity and weight gain [46]. Preliminary evidence supports the objective of maintaining high pre-diagnosis physical activity levels and a healthy body for better quality of life after breast cancer [45]. Therefore, studies investigating the most appropriate exercise programs which improve body composition and quality of life in breast cancer survivors are necessary.

Various studies have investigated the effects of different exercises modalities on body composition in breast cancer survivors during their rehabilitation phase. Exercise interventions including 150–225/min of moderate-to-vigorous aerobic exercise per week [18] or weight training [32] have been shown to improve body composition. In contrast, no significant changes in body composition have been observed after unsupervised light to moderate aerobic exercise interventions [26], resistance exercise [12], or mixed strength and endurance exercise interventions [23]. Due to these controversial findings, experts have concluded that evidence on the effects of exercise on body composition of breast cancer survivors is inconsistent [15].

Exercise in water has become increasingly popular. In fact, therapeutic aquatic exercise appears to be a safe and effective treatment modality for pain [19] and reduced mobility [15]. Water immersion decreases axial loading and, through the effects of buoyancy, allows performance of movement that may be difficult or impossible on land [4]. By using the unique properties of water (buoyancy, resistance, flow, and turbulence), a progressive exercise program from assisted to resisted movements can be created for breast cancer survivors. While the appearance or aggravation of lymphedema may reduce adherence to water exercise programs, previous studies

#### Methods and procedures

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##### Study design

The sample size was calculated on an 80 % power to detect a mean difference of 0.7 kg [17] with a standard deviation similar in both treatment groups on the lean body mass outcome, using a type 1 error ( $\alpha$ ) of 5 % and a type 2 error ( $\beta$ ) of 20 %. This power calculation resulted in 33 patients in each group. To accommodate expected dropouts before study completion, a total of 132 participants were invited to participate in this study.

The present study was a controlled clinical trial where participants were assigned to land exercise intervention, water exercise intervention, or usual-care group. For practical and ethical reasons, randomization of the patients was not feasible. We had an ethical obligation with patients who had participated as a control group in a previous study [8] to provide actual treatment. Nevertheless, due to limited resources, we created a waiting list. Therefore, patients from this waiting list agreed to be part of the usual-care group (control group) and were offered the intervention program at the end of the follow-

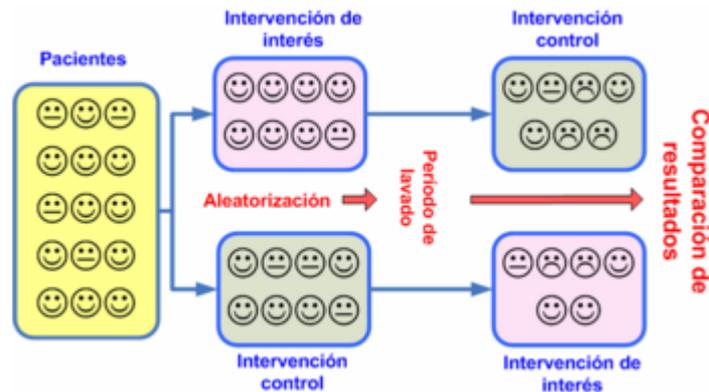
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## 8 Aleatorización

### Generación de la secuencia

La aleatorización requiere un mecanismo **gobernado por el azar** para asignar las maniobras (los tratamientos) a los sujetos bajo investigación.

Los ensayos clínicos reales deben utilizar métodos verificables de aleatorización, de tal manera que después del estudio el investigador pueda demostrar que la asignación se **mantuvo libre de sesgo**.



Aleatorización Cruzada



## Aleatorización clásica

# 8 Aleatorización

## Método para generar la secuencia aleatoria

**Cuadro VII**  
**EJEMPLO DE ALEATORIZACIÓN EN BLOQUES**  
**BALANCEADOS**

Tabla de números	2	4	6	1	3	5
8467893 5489631	A	B	A	B	A	B
0236792 4568972	A	B	B	A	B	A
2467810 1348392	B	A	A	B	B	A
3112348 3476812	B	A	B	A	A	B
5912902 0981345						
7645690 3289732						
5674389 2310398						
2938001 3289923						
1345698 4728625						
3298567 1223938						
3490594 1309093						
5489207 4532904						
	Pacientes					
	1. B	5. A	9.	13.	17.	21.
	2. A	6. A	10.	14.	18.	22.
	3. B	7. B	11.	15.	19.	23.
	4. A	8. B	12.	16.	20.	24.

## 10 Quien genero la secuencia aleatoria

Quien enrolo participantes

Quien los asigno a los grupos

### 2. Design, Randomization, and Allocation

A randomized controlled clinical trial was conducted.

Eligible participants, after providing written informed consent, were randomly assigned into 2 groups: multimodal exercise group or a control group who received the usual care treatment for breast cancer.

For ethical implications, those participants allocated to the control group, who finished the period of 6 months for the current study, were invited to be included into a new multimodal program or received an intervention by multimedia electronic document including exercises of all therapeutic sessions.

We allocated patients to a multimodal program or control **group in 4 randomization cycles**, using **computer-generated numbers**.

The sequence was **entered into numbered opaque envelopes** by **an external member** and they were opened after completion of the baseline assessment.

## 11 Método Enmascaramiento

Como se efectuó el enmascaramiento

Como se evaluó el enmascaramiento



Se trata de **técnicas de enmascaramiento** que pretenden evitar que las expectativas del paciente, del médico/investigador o del propio evaluador, influyan sobre el resultado observado.

✓ **Simple ciego:** El paciente, pero no el investigador/médico, desconoce el grupo al que ha sido asignado, es decir, ignora cuál de los posibles tratamientos recibe.

✓ **Doble ciego:** El investigador/médico y paciente desconocen el grupo de asignación de este último.

✓ **Triple ciego:** El análisis y evaluación de los datos se hace sin conocer la identidad de los grupos

## 12 Estadística

Métodos estadístico usados para comparar grupos

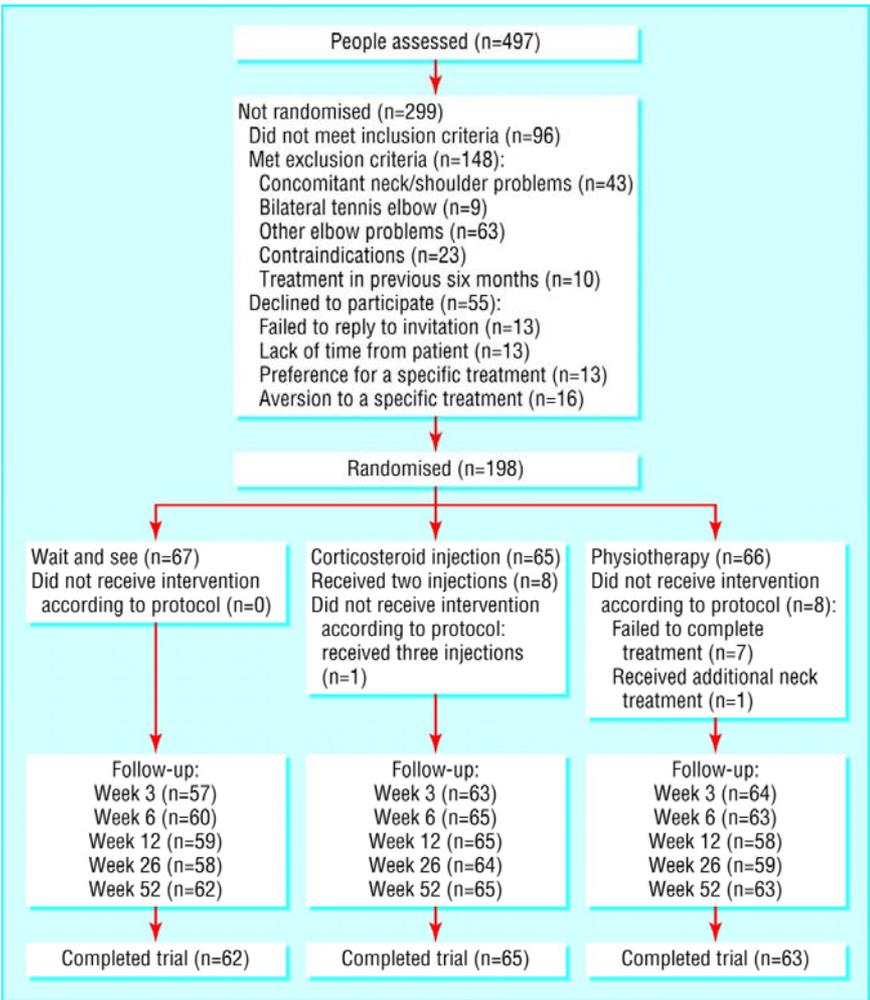


# 13 Resultados (Flujo de Participantes)

Nº individuos en cada momentos del estudio

Descripción de desviaciones

Diagrama de flujo



## 14 Resultados (Reclutamiento)

Fechas de reclutamiento

Fechas de seguimiento



## 15 Resultados (Datos Basales)

Datos demográficos

Datos clínicos iniciales

**Table 2**

Patient's characteristics and comparisons between both breast cancer survivor groups.

<b>Variable</b>	<b>Control Group (<i>n</i> = 35)</b>	<b>CUIDATE program (<i>n</i> = 32)</b>	<b><i>P</i> value</b>
Age (y), mean (SD)	48 (9)	49 (9)	0.415
Time after treatment, <i>n</i> (%)			
<12 months	29 (82.9)	22 (68.8)	0.176
>12 months	6 (17.1)	10 (31.3)	
Civil status, <i>n</i> (%)			
Married	21 (60.0)	20 (62.5)	0.718
Unmarried	8 (22.9)	5 (15.6)	
Divorced	6 (17.1)	7 (21.9)	
Educational level, <i>n</i> (%)			
Low	13 (37.1)	11 (34.4)	0.481

## 15 Resultados (Datos Basales)

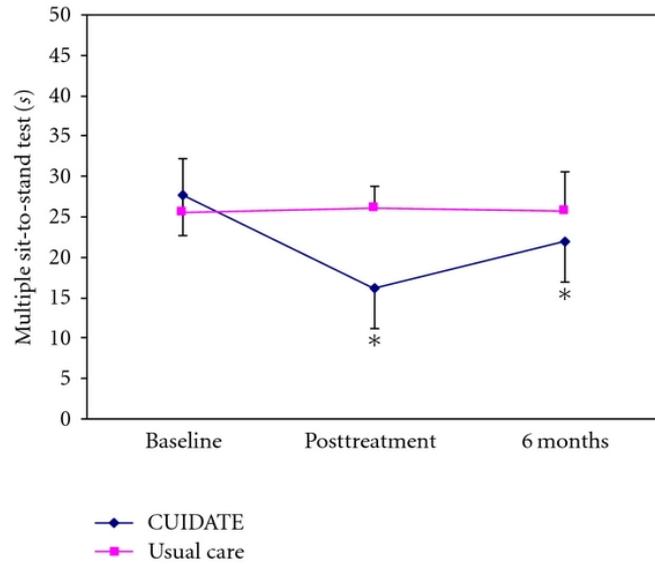
Datos demográficos

Datos clínicos iniciales

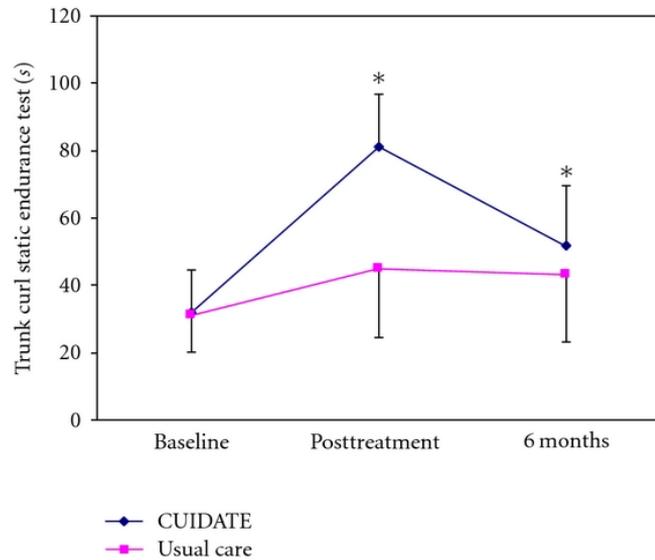
**Table 3**

Comparison of Profile of Mood State (POMS) data among healthy reference women and breast cancer survivors at baseline.

<b>POMS</b>	<b>Healthy women (n = 43)</b>	<b>CUIDATE program (n = 32)</b>	<b>CONTROL group (n = 35)</b>	<b>P CUIDATE versus control</b>
Tension-anxiety <sup>a</sup>	37.93 ± 8.71	49.00 ± 10.44	50.14 ± 10.18	0.65
Depression-dejection <sup>a</sup>	42.56 ± 7.14	52.39 ± 12.14	52.42 ± 11.01	0.99
Anger-hostility <sup>a</sup>	46.66 ± 6.89	55.17 ± 11.99	57.03 ± 14.12	0.53
Vigor <sup>a</sup>	57.43 ± 6.61	48.17 ± 7.08	49.19 ± 6.47	0.52
Fatigue <sup>a</sup>	39.90 ± 5.61	51.48 ± 10.85	54.19 ± 10.09	0.24
Confusion <sup>a</sup>	32.86 ± 4.53	42.35 ± 9.68	44.30 ± 9.70	0.53
Disturbance <sup>a</sup>	-14223 ± 2743	-19942.85 ± 5901.69	-20845.15 ± 5299.82	0.61



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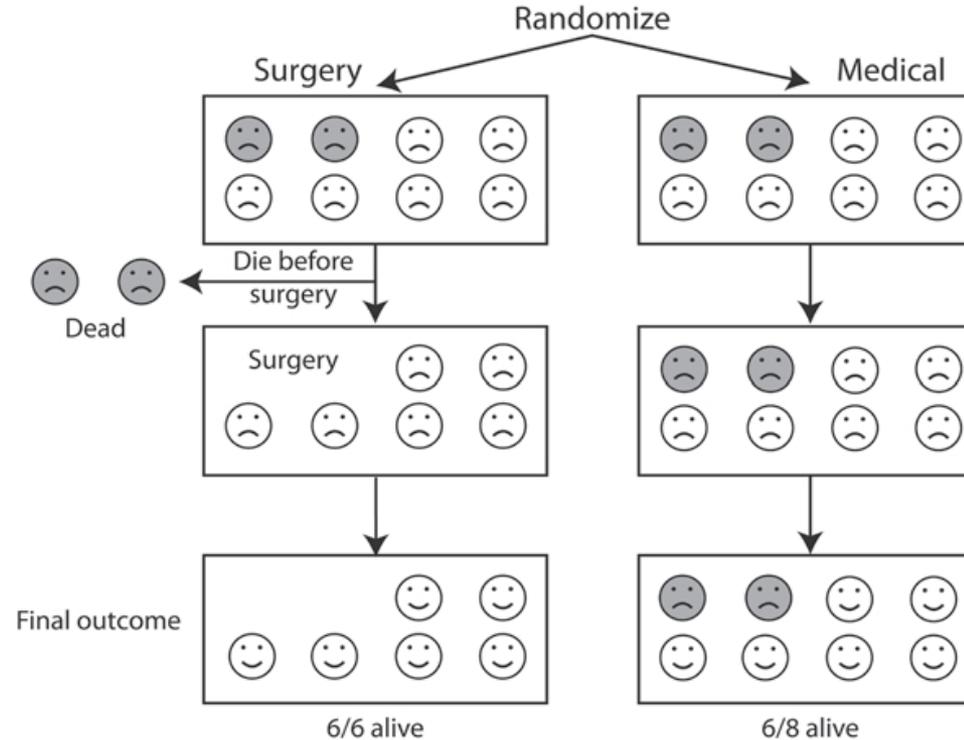
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**16 Resultados: Números Analizados**  
 Números de participantes en cada grupo  
 Análisis por “intención de tratar”

## 16 Resultados: Números Analizados

Análisis por “intención de tratar”

Forma de análisis estadístico de los resultados que incluye a todos los pacientes que han sido inicialmente asignados a cada grupo de **tratamiento independientemente de que completaran o no el periodo de tratamiento y/o seguimiento.**



## 16 Resultados: Números Analizados

Análisis por “intención de tratar”

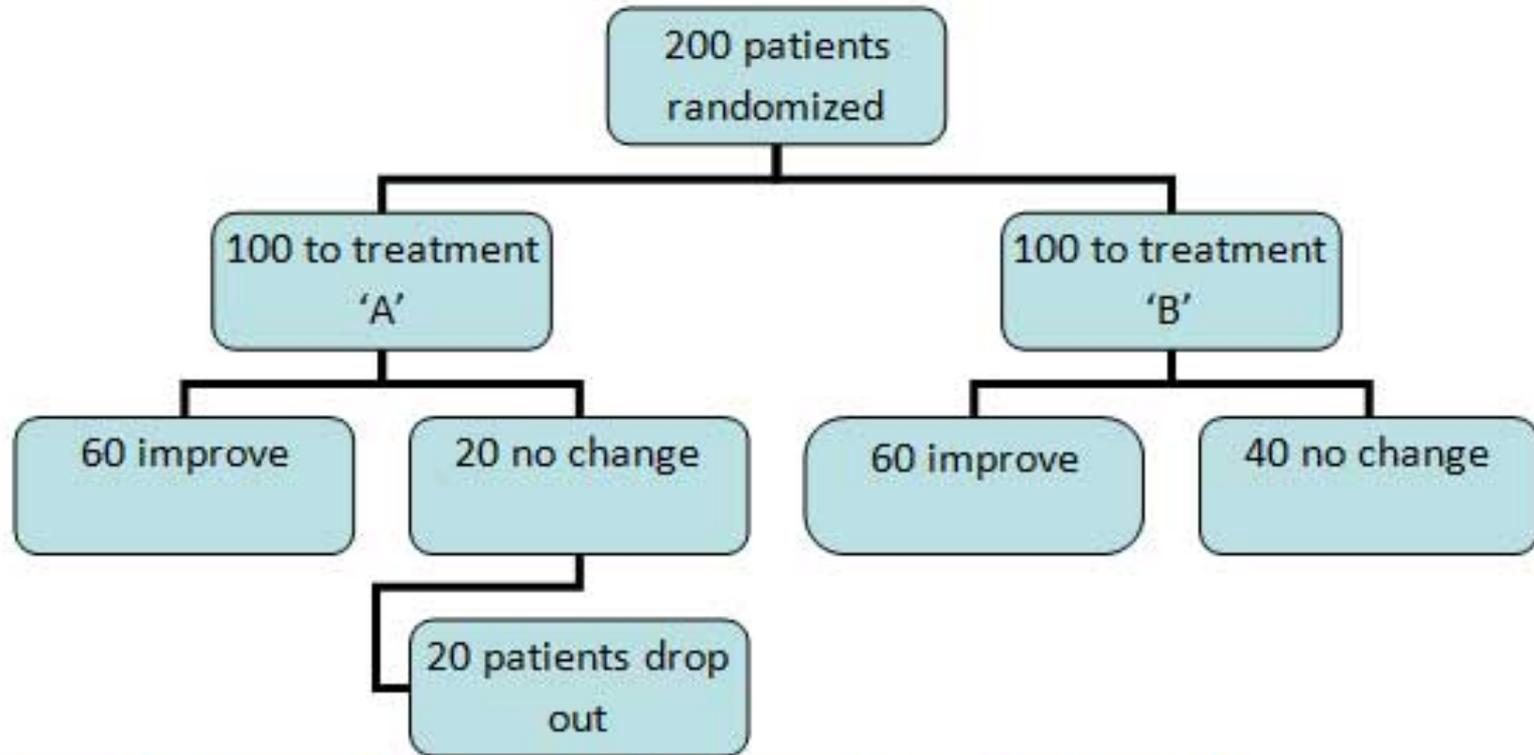


Figure 3 - If the dropouts are not considered in the analysis a false outcome is possible.

## 16 Resultados: Números Analizados

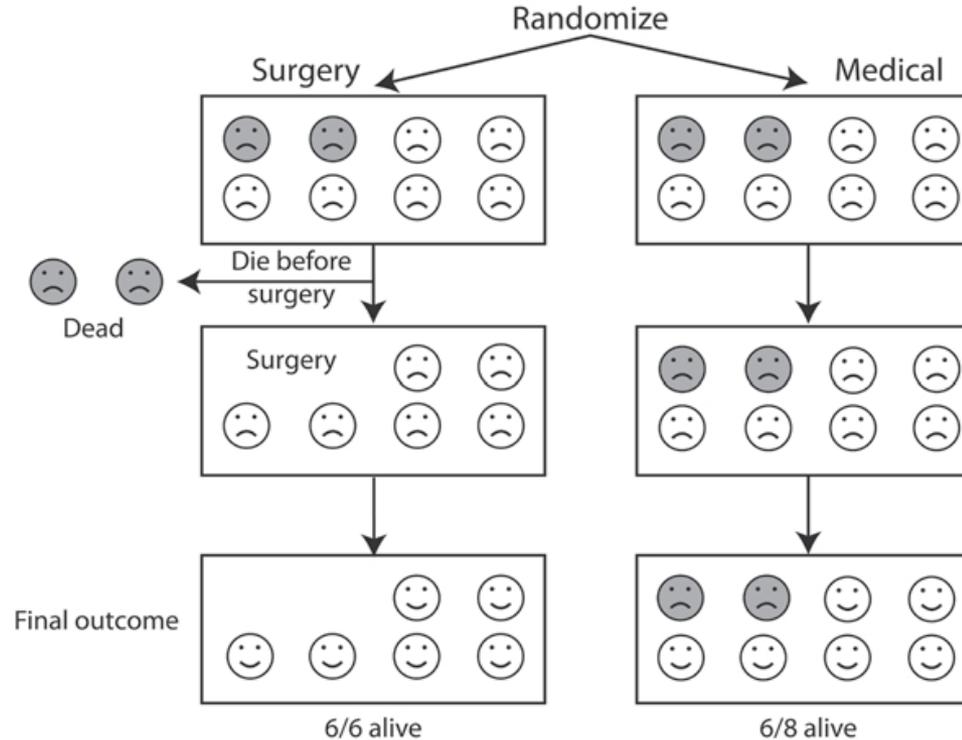
### Análisis por “intención de tratar”

Resultado ITT	Resultado PP	Interpretación
Favorable	Favorable	Favorable al tratamiento en estudio
Favorable	Desfavorable	Desfavorable al tratamiento en estudio
Desfavorable	Favorable	Analizar la razón de la discrepancia (valorar si se trata de abandonos por falta de adherencia, por pérdida de seguimiento, por aparición de eventos adversos...)
Desfavorable	Desfavorable	Desfavorable al tratamiento en estudio

## 16 Resultados: Números Analizados

Análisis por “intención de tratar”

Forma de análisis estadístico de los resultados que incluye a todos los pacientes que han sido inicialmente asignados a cada grupo de **tratamiento independientemente de que completaran o no el periodo de tratamiento y/o seguimiento.**



## 17 Resultados: Estimación Precisión de las estimaciones

**Table 2**

Median values and standard deviation values of outcome measures at each time point

Outcome measure	Group allocation	Baseline	Week 20	Week 24	Week 30	Percent change from baseline week
Pain VAS	Control	7 (1.9)	6 (2.3)	6 (2.1)	6 (2.4)	23% Improvement
	Experimental	7 (2.1)	3 (2.3)* φ	4 (2.6)* *φ	5 (2.5)*	50% Improvement
McGill Pain Questionnaire PRI	Control	23 (10.21)	20 (12.47)	21 (11.53)	22 (10.06)	17% Improvement
	Experimental	19 (11.34)	12 (7.45)* φ	14 (10.04)* *φ	19 (12.19)	40% Improvement

**Table 4**

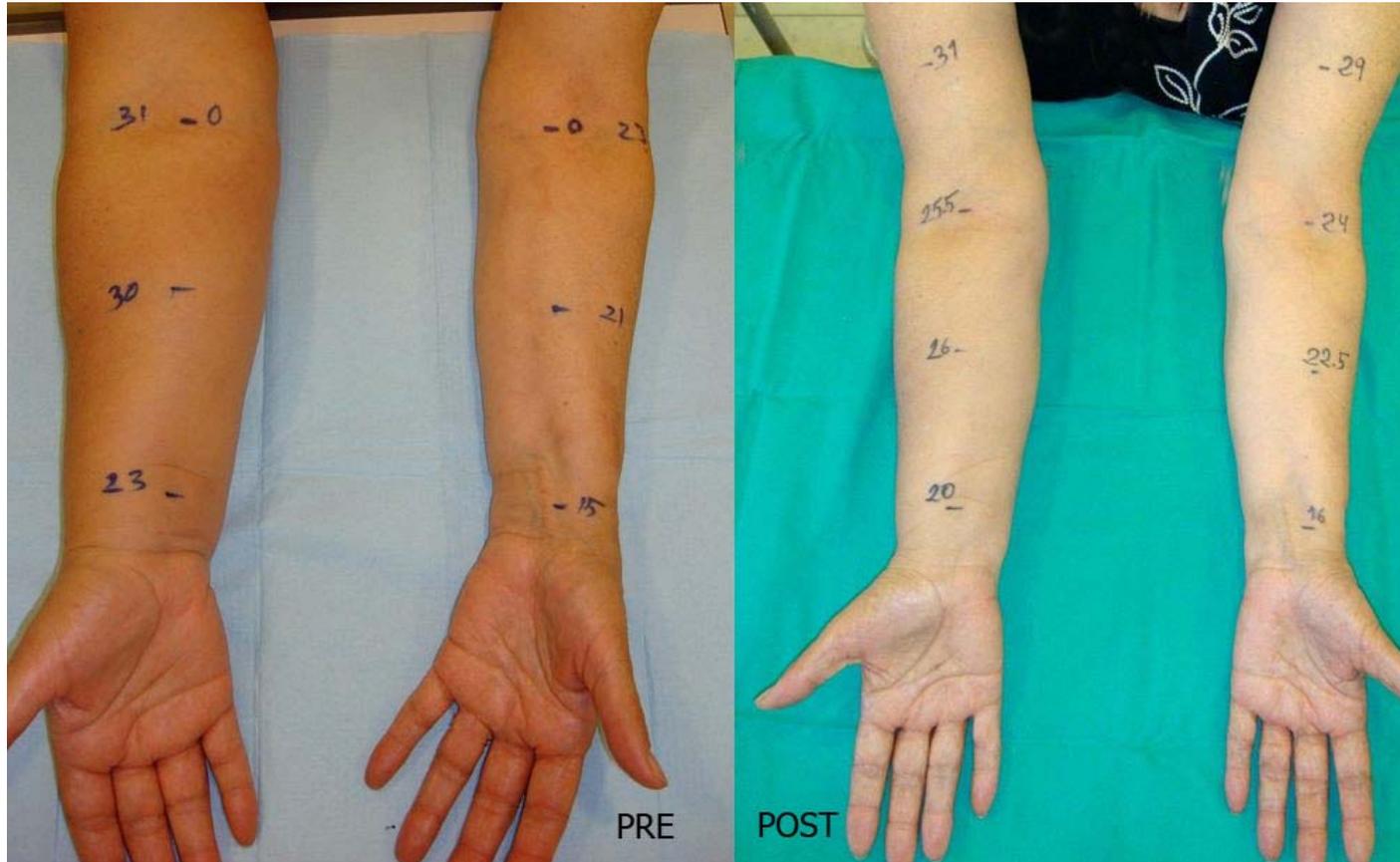
Preintervention, postintervention, and change scores for mean values of POMS.

Group	CUIDATE program	Control	Between-group differences
Tension-anxiety			
Preintervention	49.00 ± 10.44	50.14 ± 10.18	
Postintervention	39.33 ± 8.08	49.80 ± 10.32	
6 months followup	43.53 ± 9.62	51.12 ± 11.08	
Within group change scores			
Pre-post intervention	-9.66 (-13.45; -5.83)	-0.34 (-2.95; 2.26)	-9.32 (-13.79; -4.85)*
Pre intervention-6 months follow up	-5.89 (-2.53; -9.54)	-0.28 (-2.76; 6.26)	-6.17 (-1.71; -10.63)

## **18 Resultados: Análisis Auxiliar Ajustados / Controlados / Subgrupos**



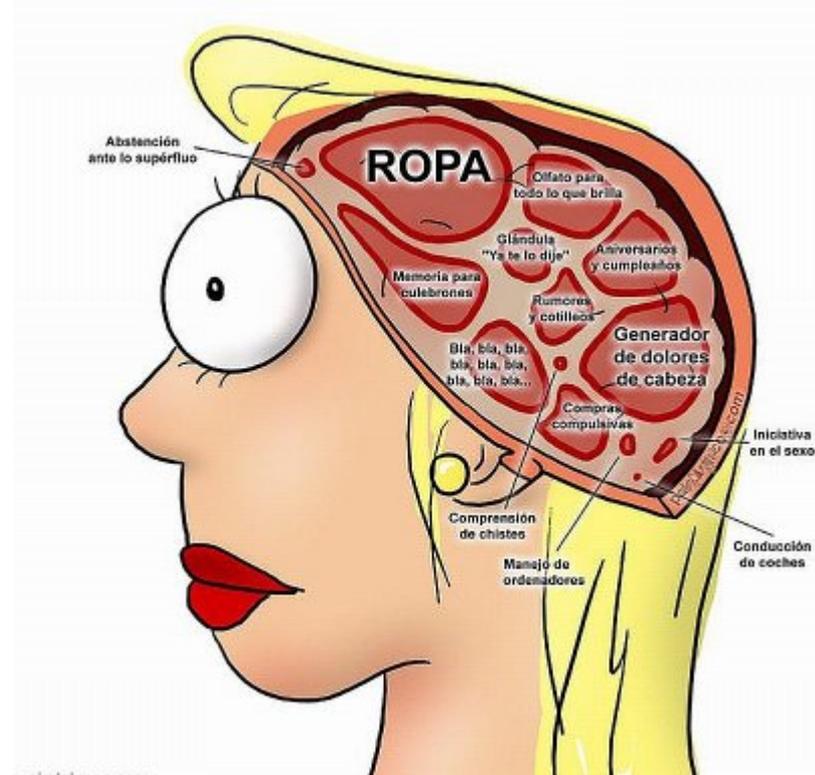
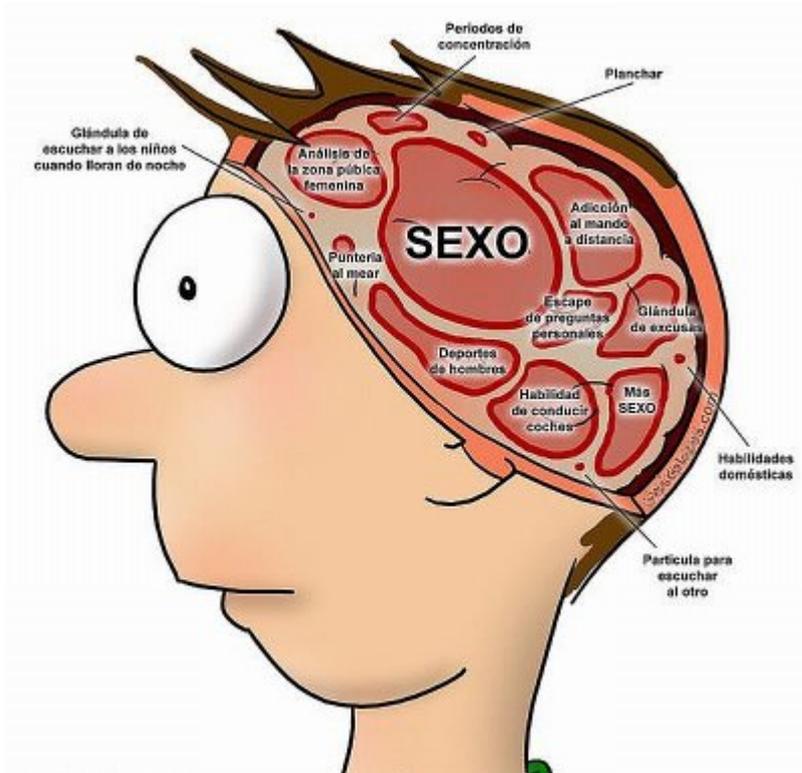
## 19 Resultados: Información resultados adversos



## 20 Comentarios: Interpretación

Interpretacion en f(x) hipotesis

Presencia de sesgos



## 21 Comentarios: Generalizabilidad

Validez externa de resultados



**¿Para que estos criterios?  
EVALUAR CALIDAD DE RCTs**

