Evaluación de la validez interna de un ensayo clínico

Efficacy of home-based peer counselling to promote exclusive breastfeeding: a randomised controlled trial

Ardythe L Morrow, M Lourdes Guerrero, Justine Shults, Juan J Calva, Chessa Lutter, Jane Bravo, Guillermo Ruiz-Palacios, Robert C Morrow, Frances D Butler-Ross

Lancet 1999;353:1226–31

Las necesidades de información clínica *("lagunas del conocimiento")*:

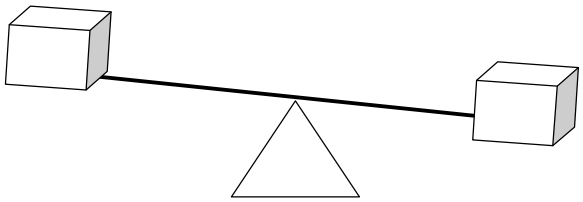
- Diagnóstico
- Etiología
- Pronóstico
- Factor de riesgo
- **Tratamiento/Prevención**

Una de las áreas más frecuentes

¿Hacer lo ***bueno*** o lo ***mejor***?
efectividad y eficiencia

Óptimo balance entre…

Beneficios



riesgos, molestias, costes

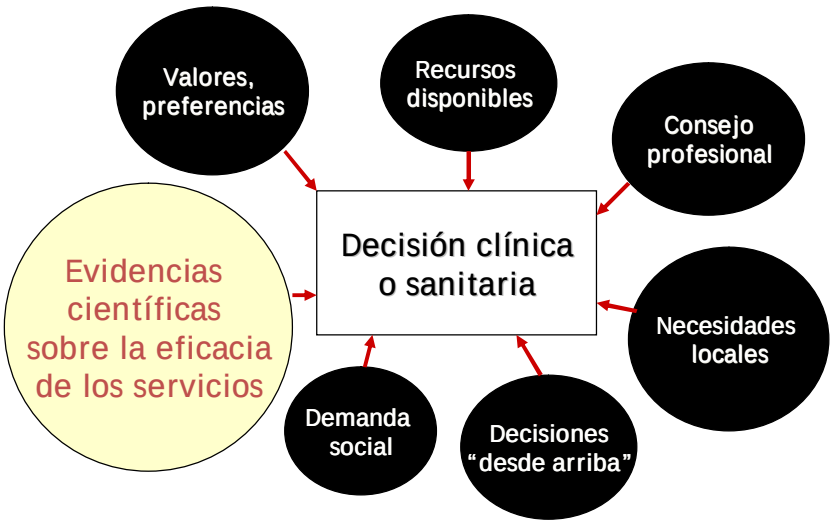
¡Entre todas las alternativas disponibles!

Aumento de la "presión" sobre los recursos sanitarios

Decisiones basadas en opiniones → Decisiones basadas en evidencias científicas

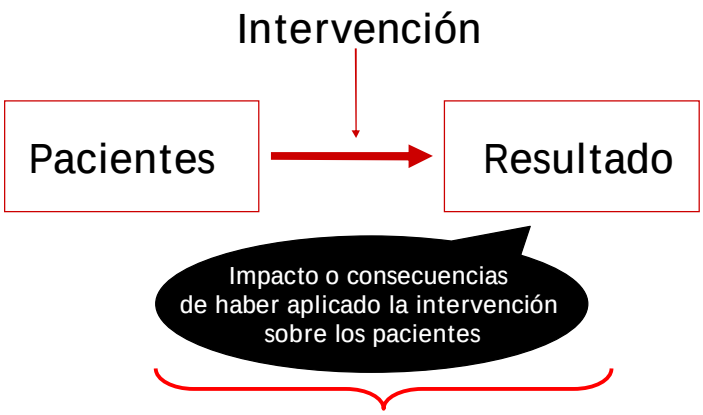
(è conocimiento validado)

¿Qué influye en la toma de decisiones clínicas y sanitarias?



Necesitamos evidencias sobre efectividad clínica

Efectividad clínica: ¿qué es?



Eficacia: condiciones experimentales ideales (máximo control)

Efectividad: condiciones de práctica clínica real

¿Dónde encontramos información sobre efectividad clínica?

- Experiencia personal
- Razonando a partir de la ciencia clínica (razonamiento fisiopatológico)
- Preguntando a colegas u otros expertos
- Pruebas publicadas (libros y artículos)

Tipos de evidencia

- Descriptiva
  - Transversal, longitudinal
- Analítica
  - Estudios de casos y controles
  - Estudios de cohortes
- Experimental
  - Ensayos clínicos aleatorizados y controlados

La jerarquía de la evidencia científica para cuestiones terapéuticas

¡Los ensayos clínicos controlados y aleatorizados son el "patrón oro" para juzgar si un tratamiento induce más beneficio que daño!

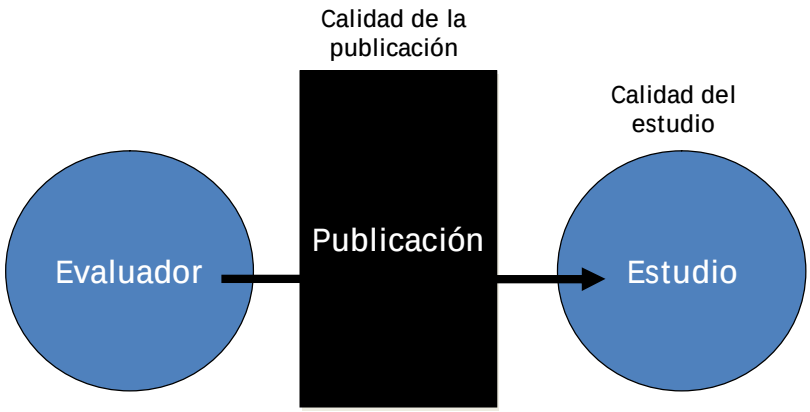
Ensayo clínico

- Prospectivo
- Controlado
- Asignación aleatoria
- Enmascaramiento (***evaluación a ciegas***)

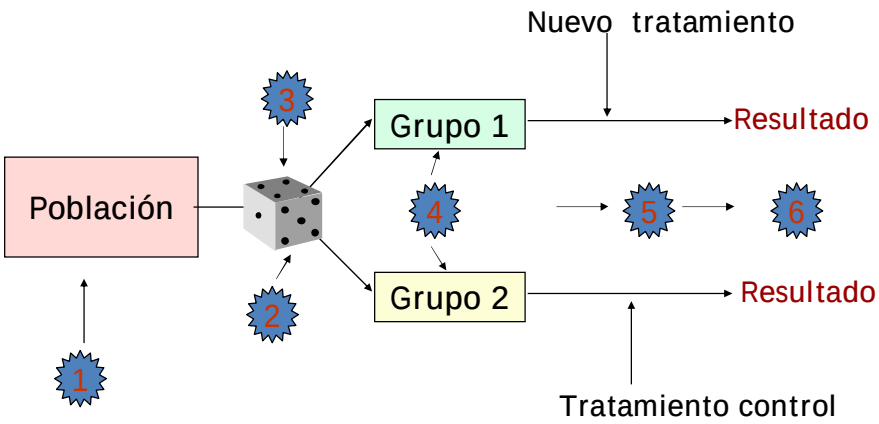
Ensayo clínico

- Comparabilidad (inferencia causal).
- Estandarización de los procedimientos (intervenciones y mediciones de las variables).
- Objetividad en las valoraciones.

Valoración de la calidad



Ensayos clínicos aleatorizados y controlados

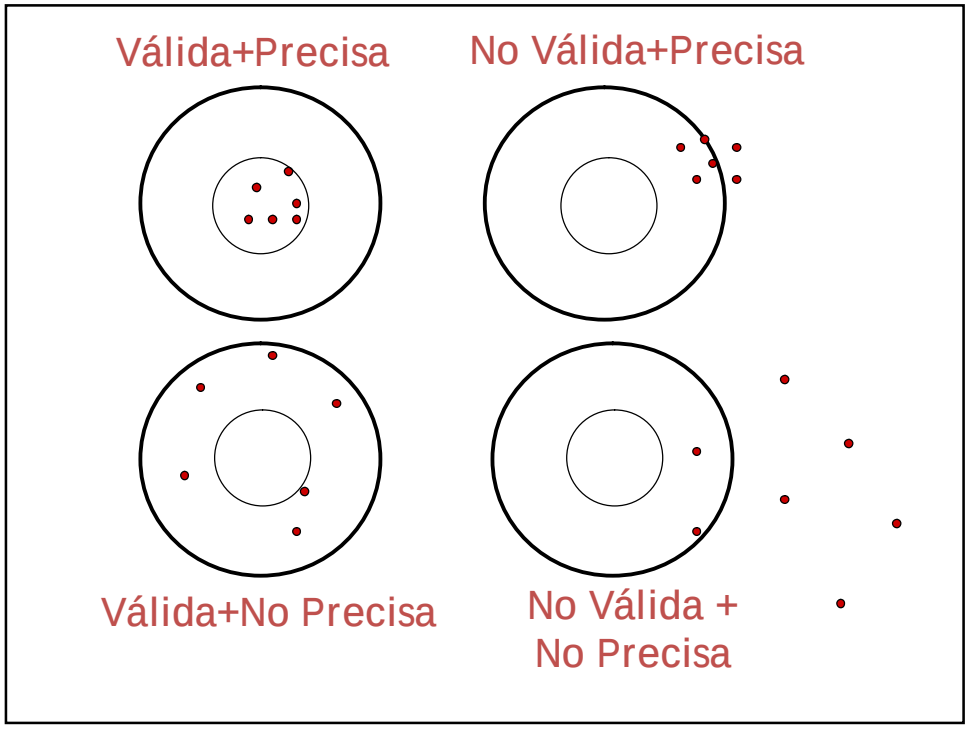


A. ¿Son válidos los resultados del estudio?

B. ¿Cuáles son los resultados?

C. ¿Ayudarán los resultados en la asistencia de mis pacientes?

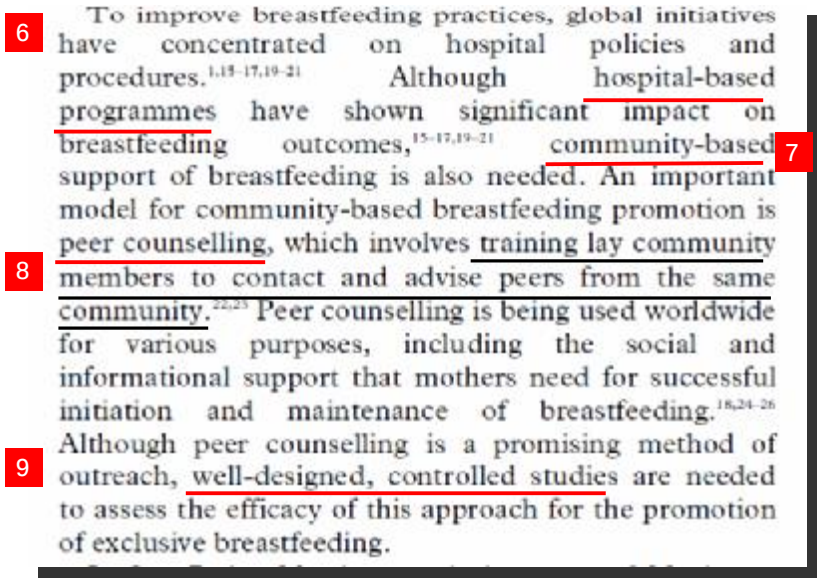
A. ¿Son válidos los resultados del estudio?



Antecedentes (1)

1 The promotion and support of breastfeeding is a global priority.[1–3] A vast scientific literature demonstrates substantial health, social, and economic benefits 2 associated with appropriate breastfeeding, including lower infant morbidity and mortality from diarrhoea and other infectious diseases.[3–11] Experts agree that exclusive breastfeeding 3 (ie, breastmilk as the sole source of food) is the ideal method of feeding infants up to about 6 months of age, after which breastfeeding should be continued but complemented with other sources of 4 nutrition.[2] Nevertheless, exclusive breastfeeding remains uncommon, even in countries with high rates of breastfeeding initiation.[12,13] Programmes 5 that increase breastfeeding do not necessarily improve the rate of exclusive breastfeeding.[14–19]

Antecedentes (2)



6 To improve breastfeeding practices, global initiatives have concentrated on hospital policies and procedures.[1,13–17,19–21] Although hospital-based programmes have shown significant impact on breastfeeding outcomes,[15–17,19–21] community-based 7 support of breastfeeding is also needed. An important model for community-based breastfeeding promotion is peer counselling, which involves training lay community 8 members to contact and advise peers from the same community.[22,23] Peer counselling is being used worldwide for various purposes, including the social and informational support that mothers need for successful initiation and maintenance of breastfeeding.[18,24–26] 9 Although peer counselling is a promising method of outreach, well-designed, controlled studies are needed to assess the efficacy of this approach for the promotion of exclusive breastfeeding.

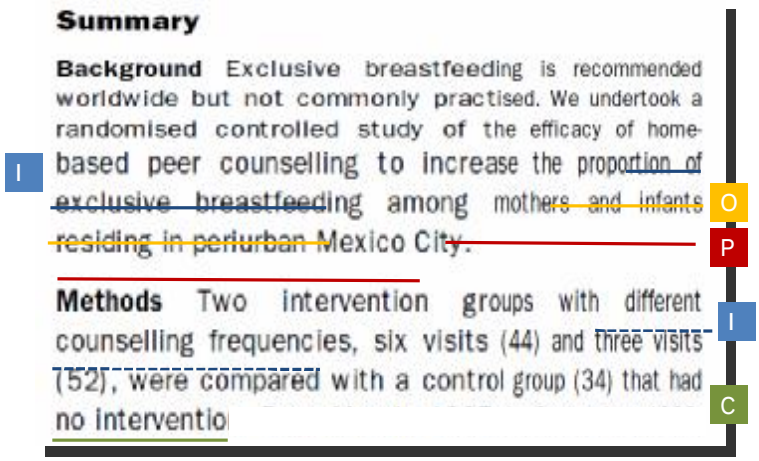
Justificación del estudio ***(tomado de la Discusión)***

- Most breastfeeding promotion programmes have been **hospital-based** owing to the opportunity to reach many mothers and to establish successful breastfeeding from the moment of birth.
- However, **community-based** approaches are needed for early counselling and follow up.
- **Peer counsellors** offer a potentially less costly outreach model than use of professional staff.
- They should not be expected to have a professional background, but should be given **sufficient training** to provide accurate information and problem-solving support to mothers.
- In general, peer counsellors should be natural helpers who are respected, trusted, in control of their own life circumstances, and responsive to the needs of others.

1. ¿Se hizo el estudio sobre un tema claramente definido?

- Población
- Intervenciones
- Resultados de interés

¿Cuál es la pregunta que trata de contestar el estudio? (P – I – C – O)



Summary

Background Exclusive breastfeeding is recommended worldwide but not commonly practised. We undertook a randomised controlled study of the efficacy of home-based peer counselling to increase the proportion of exclusive breastfeeding among mothers and infants residing in periurban Mexico City.

Methods Two intervention groups with different counselling frequencies, six visits (44) and three visits (52), were compared with a control group (34) that had no interventio

I

O

P

I

C

¿Cuál es la pregunta que trata de contestar el estudio? (P – I – C – O)

We undertook a randomised controlled trial in the San Pedro Martir area to examine the hypothesis that home visits by peer counsellors to pregnant and lactating women would significantly increase the rate of exclusive breastfeeding, and that more frequent visits would result in a higher rate of exclusive breastfeeding. In addition, we examined the efficacy of an intervention to increase breastfeeding duration and to decrease the risk of infant diarrhoea.

I

I

P

O

O

Hipótesis

We undertook a randomised controlled trial in the San Pedro Martir area to examine the hypothesis that home visits by peer counsellors to pregnant and lactating women would significantly increase the rate of exclusive breastfeeding,

Statistical analysis

On the basis of primary hypothesis, we calculated the minimum required sample size to be 120 participants, setting α=0·05, and a one-sided test of hypothesis. This sample size gave 86% power to detect a 20% absolute difference in exclusive breastfeeding in intervention versus control participants (24% *vs* 4%), if there was no design effect, or 76% power to detect the same difference if there was a design effect of 1·2.[29]

Población de estudio

- **Pregnant women** residing in the San Pedro Mártir area (Mexico)
- Study mothers were identified by a semiannual door-to-door census and continuous reporting of new pregnancies in the community by study staff and mothers.

Intervención (1)

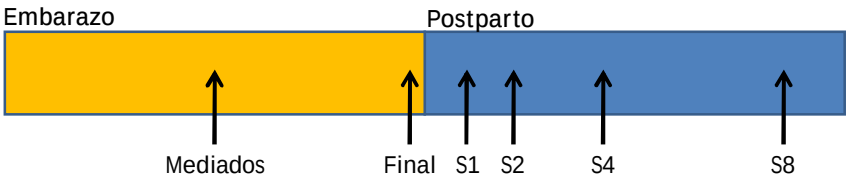
- **Home-based peer counselling**

  4 Mother–infant pairs in the intervention groups received either six or three home visits from peer counsellors.

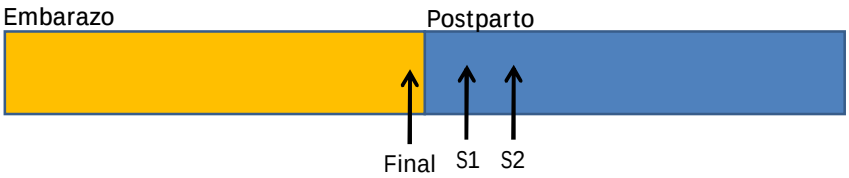
- Furthermore, peer counsellors were permitted to respond to occasional requests for additional support that were initiated by intervention-group mothers.

Intervención (2)

- Six-visit group:



- Three-visit group:



Intervención (3)

Three women who had previously worked for the Instituto Nacional de la Nutricion as field data collectors were trained to promote breastfeeding as peer counsellors. Each was a resident of San Pedro Martir, aged 25–30 years, had a high-school education, and had a commitment to breastfeeding, although they did not necessarily have previous personal breastfeeding experience. These peer counsellors were trained and supervised by staff of La Leche League of Mexico and the physician study coordinator (MLG), who was also trained in lactation management. The peer-counsellor training consisted of 1 week of classes, 2 months in lactation clinics and with mother-to-mother support groups, and 1 day of observation and demonstration by visiting experts. Finally, the peer counsellors practised in a neighbourhood nearby San Pedro Martir for 6 months before the intervention trial, during which the content of messages and problem-solving skills were refined.

Intervención (4)

A rapid ethnographic study of infant feeding was done in San Pedro Martir before the intervention trial to guide educational approaches.[27] A set of visual aids was developed specifically for this project on the basis of existing materials of La Leche League. Home visits to pregnant women focused on the benefits of exclusive breastfeeding, especially during illness; basic lactation anatomy and physiology; positioning of the infant and "latching on"; common myths; typical problems and solutions; and preparation for birth. Postpartum visits with the mother focused on establishing a healthy breastfeeding pattern, addressing maternal concerns, and providing information and social support. Key family members who could provide support to mothers also were included in these counselling visits.

Comparación

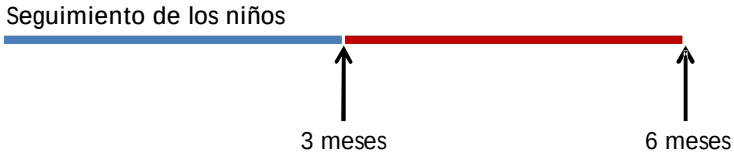
- Control group – no intervention

Control-group mothers with lactation problems were referred to their own physicians.

[No other sources of breastfeeding counselling were available in the community.]

Outcomes

- Exclusive breastfeeding [3 meses]
- Diarrhoea [3 meses]
- Duration of any breastfeeding [6 meses]



Definiciones de los outcomes

The primary study outcome was exclusive breastfeeding, defined as giving maternal milk at the only infant food source in the previous week, with no other liquids or food given.[28] Secondary outcomes were duration of breastfeeding, the proportion of infants who had an episode of diarrhoea in the first 3 months (cumulative incidence), and maternal satisfaction with counselling. Diarrhoea was defined as more frequent and liquid stools than normal for the infant, as reported by the mother.

2. ¿Se realizó la asignación de los pacientes a los grupos de tratamientos de manera aleatoria?

Es importante también que el sistema de aleatorización sea "opaco" (ocultación de la secuencia)

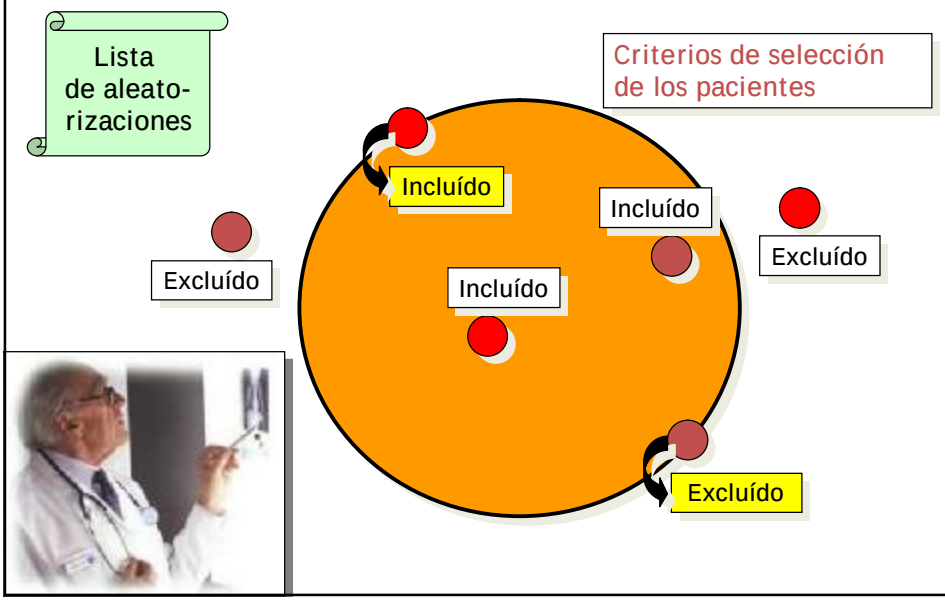
El sesgo de selección

¿Cómo asegurar que los pacientes son comparables?

Cada paciente tiene las mismas probabilidades ***a priori*** de recibir uno u otro tratamiento

Asignación aleatoria (azar)

Ocultación de la secuencia de aleatorización



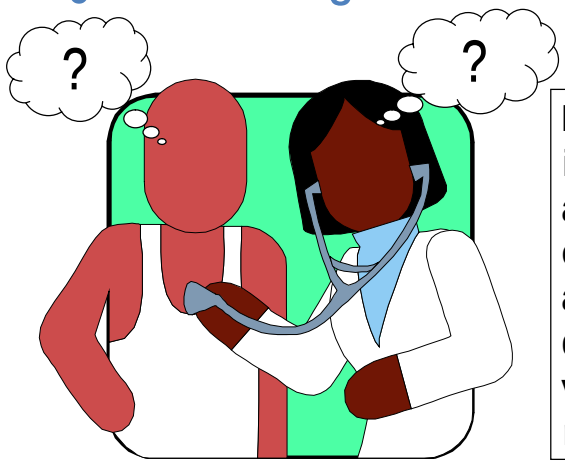
¿Cómo se asignaron las intervenciones?

- Randomised, community-based intervention trial.
- Before the study started, San Pedro Martir was mapped into 39 clusters with two to four city blocks each.
- 13 clusters were allocated randomly to each study group, stratified by subdivision.
  - *San Pedro Martir is a periurban community on the southwestern outskirts of Mexico City, compromising three subdivisions that vary in sociodemographic characteristics.*
- This randomisation schedule was generated by computer.
- Clusters rather than individuals were randomised to keep to a minimum the contamination of influences expected if relatives and close neighbours were assigned to different study groups.
- Allocation concealment from staff and participants was not possible.

3. ¿Se ha mantenido un diseño "ciego" respecto al tratamiento, tanto para los pacientes, investigadores y demás personal del estudio?

El sesgo de detección

¿Cómo asegurar la objetividad?



El paciente, el investigador o ambos desconocen el tratamiento asignado a la hora de medir las variables de resultado

Enmascaramiento de la intervención en la evaluación

¿Enmascaramiento de las intervenciones?

- Diseño abierto
- ¿Sesgo de detección? (detection bias) ⇒ entrenamiento de las entrevistadoras y entrevistas estructuradas
- ¿Sesgo de realización? (performance bias)

- *Interviewer bias was controlled by careful standardisation of procedures across study groups.*
- *Mothers were not informed of the study hypotheses.*

4. Aparte de la intervención experimental, ¿se ha tratado a los grupos de la misma forma?

Valorar las co-intervenciones

El sesgo de realización

¿Cómo asegurar la objetividad?

El paciente, el investigador o ambos desconocen el tratamiento asignado a la hora de tratar al paciente

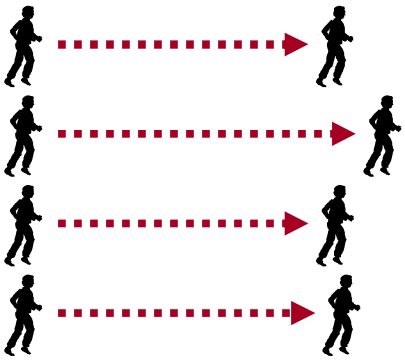
Enmascaramiento de la intervención al tratar al paciente

5. ¿Se han tenido en cuenta adecuadamente todos los pacientes incluidos en el estudio?

- ¿Se realizó un seguimiento completo de todos los pacientes?
- ¿Se comunican las pérdidas y abandonos y sus causas?
- ¿Se hizo el análisis por "intención de tratar"?

El sesgo de desgaste (*attrition bias*)

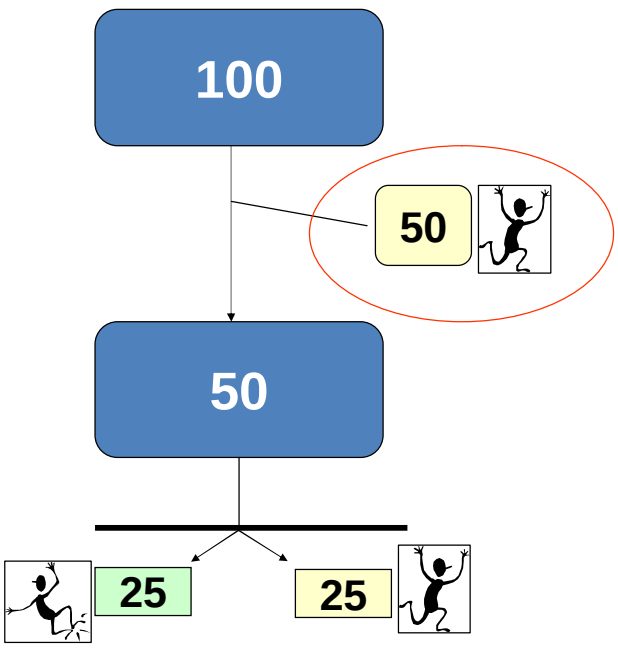
¿Cómo asegurar que el estudio es fiable?



Todos los pacientes son seguidos hasta el final del estudio de manera exhaustiva

Seguimiento prospectivo completo - Análisis por intención de tratar

Análisis por intención de tratar



Pérdidas y abandonos (1)

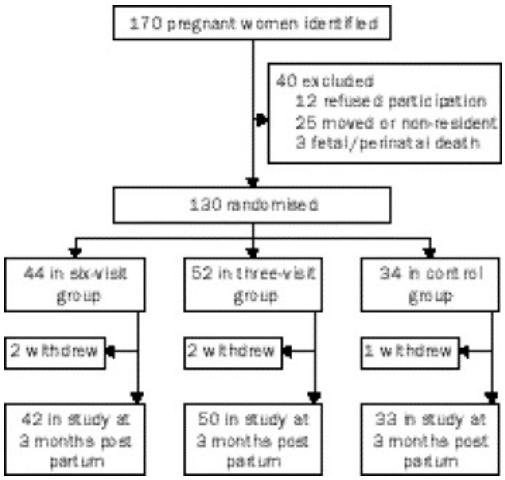


Figure 1: Trial profile

Pérdidas y abandonos (2)

- 170 pregnant women were identified in San Pedro Martir and were asked to participate.
- Of these, only 12 (7%) refused, and 28 were ineligible and excluded → −40
- Participants and non-participants did not differ by location within study area or by study group, and did not differ in socioeconomic status.
- 130 mother–infant pairs participated in the study:
  - 125 remained in the study at 3 months → −5
  - Exit interviews [6 months] were done in 117 participants: 104 at 6 months, and 13 between 3 and 6 months post partum → −13

5. ¿Eran similares los grupos al inicio del ensayo?

No importa tanto la significación estadística sino la magnitud de las diferencias

Tabla 1 descriptiva

¿Son comparables?

¿Son comparables?

¿Grupos comparables? (1)

Characteristic	Six-visit group (n=44)	Three-visit group (n=52)	Control group (n=34)
Maternal demographics			
Educational attainment			
Primary school or none	20 (45%)	20 (38%)	18 (53%)
Secondary	12 (27%)	19 (37%)	8 (24%)
Married	24 (55%)	34 (65%)	22 (65%)
Employed outside home	3 (7%)	8 (15%)	4 (12%)
Infant birthplace			
Home	4 (9%)	3 (6%)	1 (3%)
Baby-friendly hospital*	22 (50%)	27 (52%)	17 (50%)
Perinatal conditions			
Primiparous mother	13 (30%)	15 (29%)	7 (21%)
Delivery by cesarean section	10 (23%)	21 (40%)	9 (26%)
Infant birthwt gm <2500 g	5 (12%)	8 (15%)	3 (9%)
Infant roomed with mother in hospital	14 (32%)	21 (40%)	19 (56%)
Infant stay in hospital >7 days	3 (7%)	6 (12%)	3 (9%)
Infant female	27 (61%)	28 (54%)	17 (50%)
Initial breastfeeding practices			
Breastfed within a few hours of birth	29 (66%)	31 (60%)	23 (68%)
Ever breastfed	44 (100%)	51 (98%)	32 (94%)

Frequencies are presented only for selected categories and variables and therefore do not add up to 100%. *Born in a hospital certified by or before 1998 as "baby-friendly" (ie, following international standards for breastfeeding support).

Table 1: Sociodemographic characteristics and perinatal conditions of 130 study mothers and infants

¿Grupos comparables? (2)

- No significant differences were found among study groups in baseline factors, including breastfeeding initiation (table 1).
- The proportion who initiated breastfeeding within a few hours of delivery was similar in each study group.
- 35 (27%) mothers were primiparous, and 31% gave birth by caesarean section.

Lay health workers in primary and community health care for maternal and child health and the management of infectious diseases. *Cochrane Database of Systematic Reviews* 2010, Issue 3. Art. No.: CD004015.

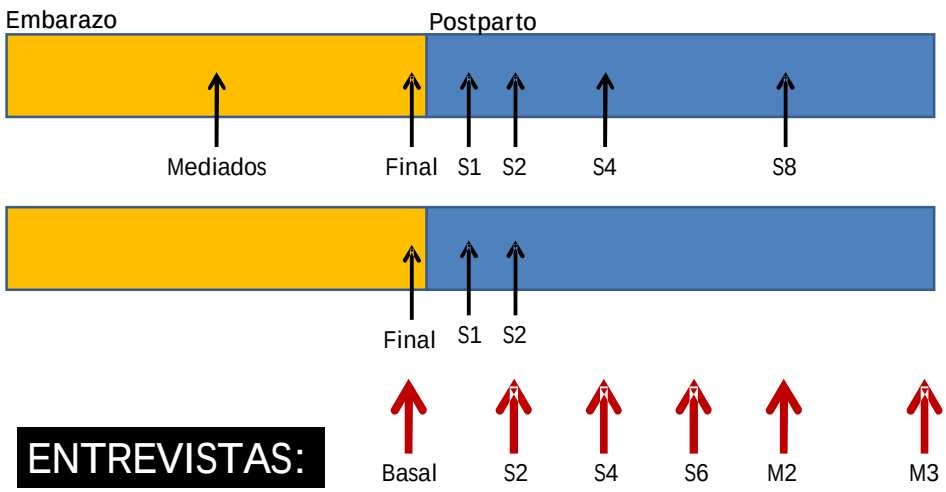
Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	'13 clusters were randomly allocated to each study group, stratified by subdivision. This randomisation schedule was generated by computer' (p1227).
Allocation concealment?	Yes	Cluster randomised: '13 clusters were randomly allocated to each study group, stratified by subdivision. This randomisation schedule was generated by computer' (p1227).
Blinding? All outcomes	No	'All data were collected...by two experienced staff other than peer counsellors. The study hypothesis could not be concealed from these staff, but they were trained to administer all questions in a standard manner, and they undertook an equal proportion of interviews in each study group' (p1227).
Incomplete outcome data addressed? All outcomes	Yes	Missing outcome data balanced in numbers across groups.
Free of selective reporting?	Unclear	Protocol not available.
Free of other bias?	Yes	

Registro de los datos (1)

- All data were collected through structured interviews of mothers residing in study households by two experienced staff other than the peer counsellors.
- The study hypothesis could not be concealed from these staff, but they were trained to administer all questions in a standard manner, and they undertook an equal proportion of interviews in each study group.
- Baseline interviews were carried out in the last trimester of pregnancy to examine *sociodemographic factors, breastfeeding history and intention*, and other factors. A perinatal questionnaire ascertained *pregnancy history, the health of mother and infant, and early infant-feeding practices.*
- Five follow-up interviews were scheduled for all study mothers at 2, 4, and 6 weeks, and at 2 and 3 months post partum to record *infant-feeding practices in the previous week and any lactation problems experienced*.

Visitas de seguimiento



Registro de los datos (2)

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- Five follow-up interviews were scheduled for all study mothers at 2, 4, and 6 weeks, and at 2 and 3 months post partum to record *infant-feeding practices in the previous week and any lactation problems experienced*.

Registro de los datos (3)

- During weeks in which both a counselling visit and a data-collection interview were due, the data-collection interview was scheduled to follow the counselling visit by 2–3 days.
- During these interviews, mothers were asked *whether the infant had experienced diarrhoea since the last interview, and to describe any episodes and whether they had taken the infant to a doctor.*
- An exit interview at 6 months post partum examined *the duration of breastfeeding and maternal attitudes towards the peer counsellors.*