# RCT HANDS ON

## RCT OR THERAPY STUDY

 Randomized controlled trial is a study in which people are allocated at random to receive one of several clinical interventions.

 On most occasions, the term "intervention" refers to treatment.

# **APPRAISING AN RCT**

- •FRISBE
- •**F**= Follow-up- is everyone accounted for?
- •R= Randomization- was assignment of patients to
  - treatment or control random? Was allocation concealed?
- •I= intention to treat analysis- were all patients analysed in the group to which they were assigned?
- •S= Similar baseline characteristics of patients- were groups similar at start of study?
- B= Blinding- were patients, health workers and study personnel "blinded" to who had treatment and who placebo/comparison?
- •E= Equal treatment- aside from the intervention was everyone treated equally?



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## **RCT APPRAISAL**

Support Care Cancer (2012) 20:1613-1618 DOI 10.1007/s00520-011-1250-5

ORIGINAL ARTICLE

#### Topical silver sulfadiazine for the prevention of acute dermatitis during irradiation for breast cancer

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Received: 16 December 2010/Accepted: 31 July 2011/Published online: 19 October 2011 © Springer-Verlag 2011

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#### GOAL

effectiveness of topical SSD. The purpose of this controlled trial was to assess the effectiveness of topical SSD as a prophylactic agent for acute radiation dermatitis in women who underwent radiotherapy for breast cancer.

## **ASSIGNMENT OF PATIENTS RANDOMIZED?**

Patients were randomized into the intervention and control groups by random allocation software [16]. Because the

# **GROUPS SIMILAR ?**

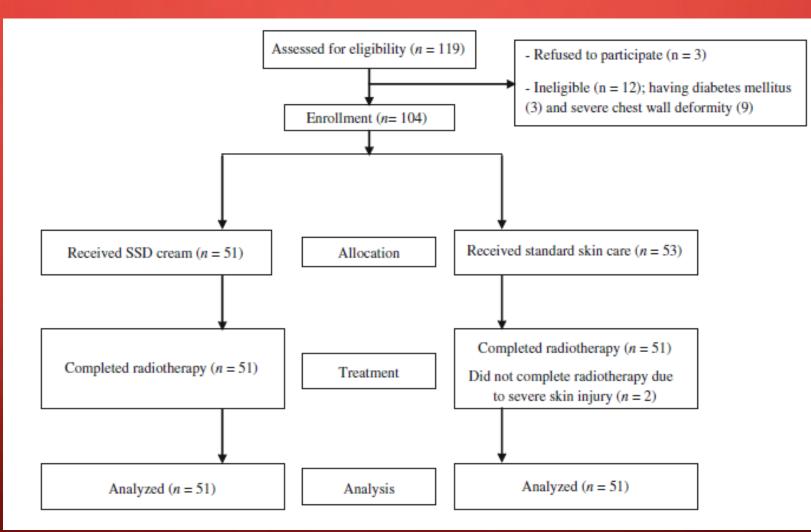
groups by random allocation software [16]. Because the anatomy of the irradiated site is a known factor influencing the severity of radiation dermatitis [4], the two groups were matched in this regard (flat or not flat chest wall based on

	SSD $n=51$	Control n=51	р
Age	48.7±10.3	48.1±9.9	0.785 *
Chest wall, flat/not flat	40/11	40/11	-
Energy, E8/E10	1/50	4/47	0.181 **
Radiation fields, one/two	42/9	45/6	0.289 **
Post. axillary field, no (%)	29 (56.8)	31 (60.7)	0.420 **

## WAS RANDOMIZATION CONCEALED ?

#### Not mentionned

#### WAS INTENTION TO TREAT USED ?



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### WHERE PATIENTS, CLINICIANS, BLIND TO TREATMENT?

intervals during radiotherapy and 1 week thereafter. The observer was a radiation oncologist who was unaware to which groups the patients belong to. Skin injury was scored

### WHERE BOTH GROUPS TREATED EQUALLY ?

Both groups received verbal instructions and a leaflet about standard skin care at the start of radiotherapy, including gentle washing of the area with baby soap and not applying a powerful soap directly to the skin, patting the area dry with a soft towel, and wearing loose clothes, preferably cotton, next to the skin. Also, they were advised not to use cosmetics, perfume, cologne, or deodorant on the area. No other prophylactic creams/lotions/gels were to be applied to the radiation field during the radiotherapy course. The compliance in applying the SSD cream and general skin care instructions was evaluated weekly by treating physician.

## FOLLOW UP LONG ENOUGH ?

		Severity of skin injury					<i>p</i> *
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	
1st wk	SSD Control	51 (100) 51 (100)	0 0	0	0 0	0	_
2nd wk	SSD Control	51 (100) 40 (78.4)	0 11 (21.5)	0	0	0	< 0.001
3rd wk	SSD Control	0 0	51 (100) 43 (83.3)	0 8 (15.6)	0 0	0 0	0.003
4th wk	SSD Control	0 0	51 (100) 29 (56.8)	0 22 (43.1)	0 0	0 0	< 0.001
5th wk	SSD Control	0 0	31 (60.7) 15 (29.4)	18 (35.2) 26 (50.9)	2 (3.9) 10 (19.6)	0 0	0.002
6th wk	SSD Control	0 0	8 (15.6) 1 (1.9)	32 (62.7) 23 (45.1)	11 (21.5) 27 (52.9)	0 0	0.001

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# IS THIS A GOOD STUDY ?