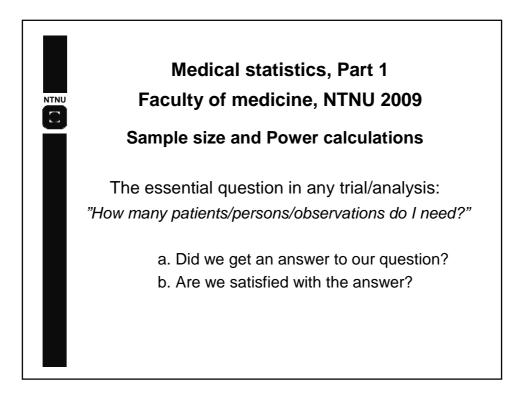


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Sample size (an example)

NTNU

"Twenty patients (10 in Arm A and 10 in Arm B) will be included initially as a "run in phase" of the study for the initial evaluation of feasibility and safety... The median survival in patients who are given (...) is taken to be 6.5 months. To detect an increase of at least 3 months in survival among patients given (...) (ie. to 9.5 months), the trial would need to recruit 50 patients; this with 70% power and a level of significance of 5% (twosided)

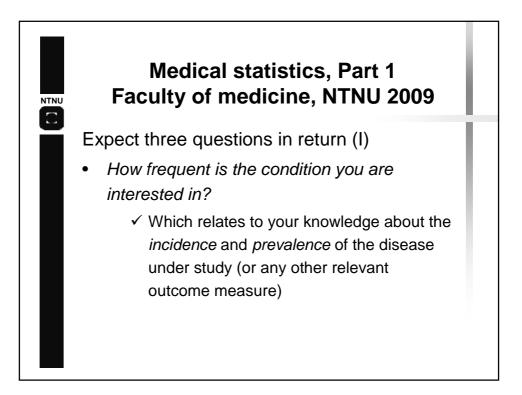


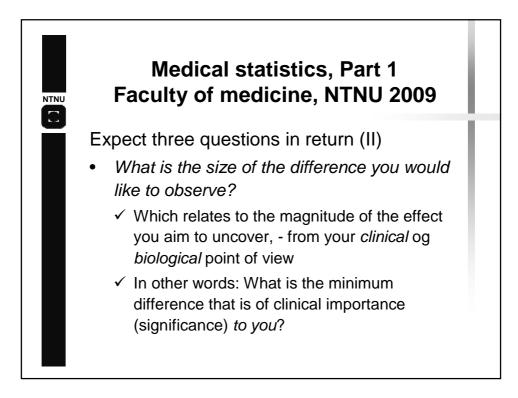
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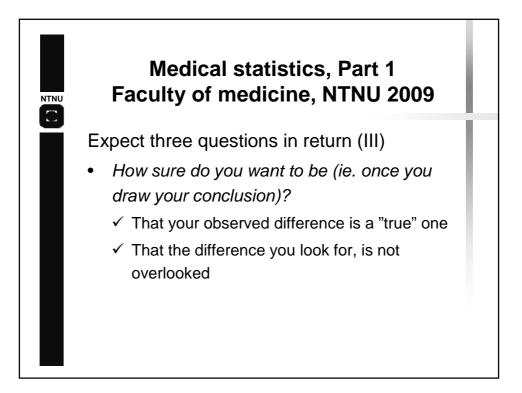
Sample size (an example)

NTNU

"Twenty patients (10 in Arm A and 10 in Arm B) will be included initially as a "run in phase" of the study for the initial evaluation of feasibility and safety... The median survival in patients who are given (...) is taken to be 6.5 months. To detect an increase of at least 3 months in survival among patients given (...) (ie. to 9.5 months), the trial would need to recruit 50 patients; this with 70% power and a level of significance of 5% (twosided)





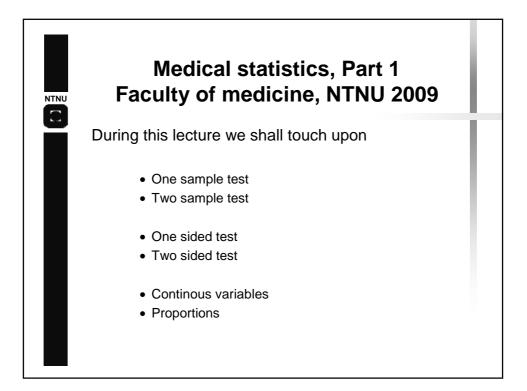


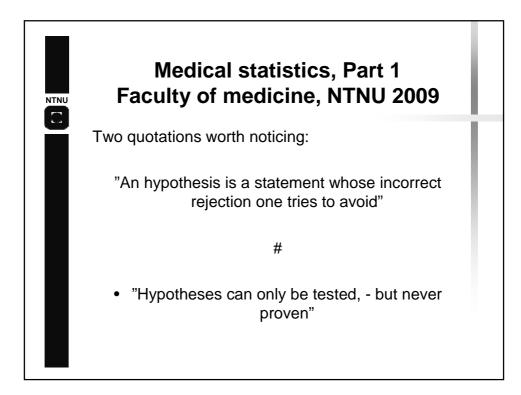
Medical statistics, Part 1 Faculty of medicine, NTNU 2009

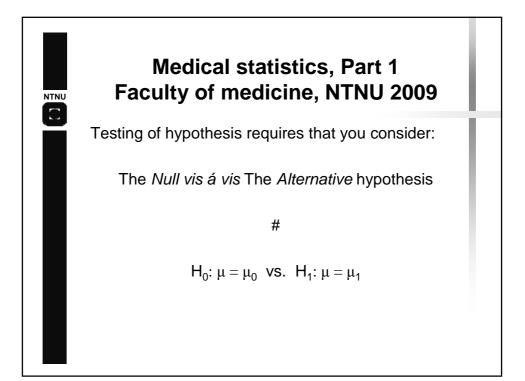
Sample size (an example)

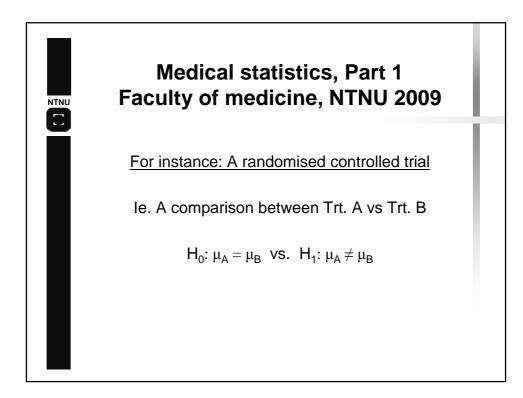
NTNU

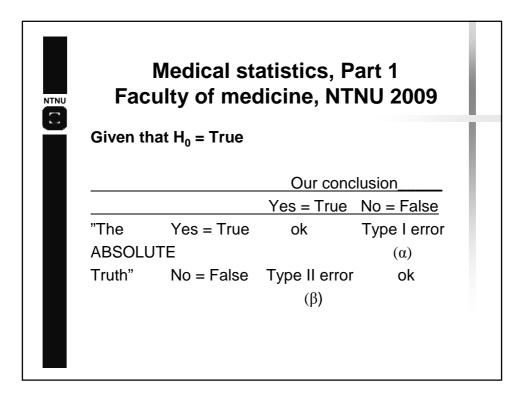
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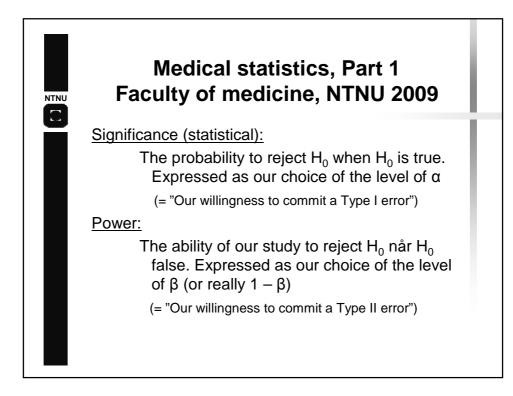


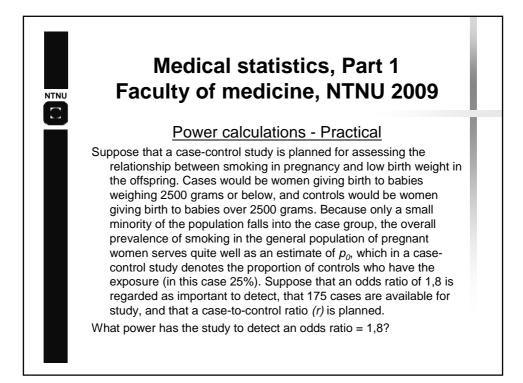


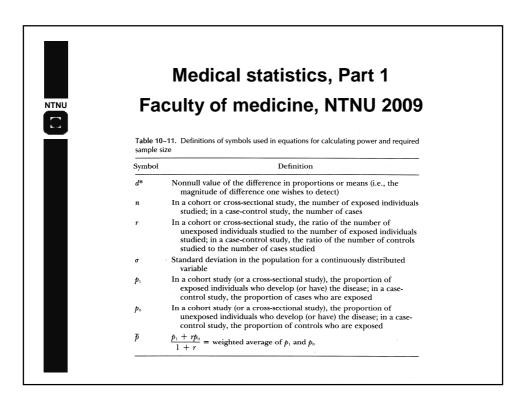












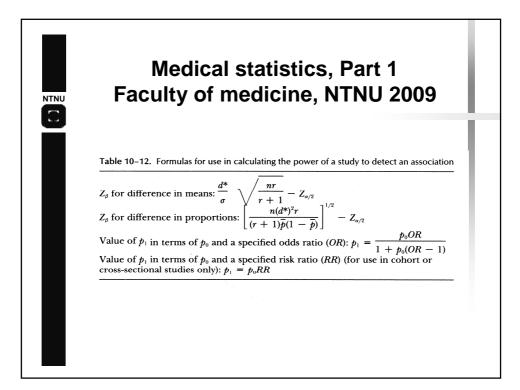
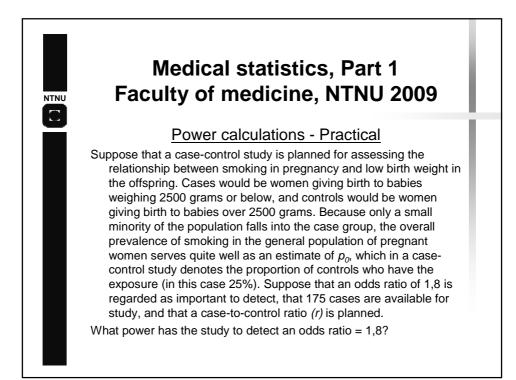


Table 10–15. Formulas for use in calculations of required sample size Difference in means: $n = \frac{(Z_{a/2} + Z_{\beta})^2 \sigma^2 (r + 1)}{(d^{*})^2 r}$ Difference in proportions: $n = \frac{(Z_{a/2} + Z_{\beta})^2 \overline{p}(1 - \overline{p})(r + 1)}{(d^{*})^2 r}$		al statistics, f medicine, N	
$n = \frac{(Z_{n/2} + Z_{\beta})^2 \sigma^2 (r+1)}{(d^{\ast})^2 r}$ Difference in proportions:	Table 10-15. Formul	s for use in calculations of required samp	ole size
Difference in proportions: $n = \frac{(Z_{n/2} + Z_{\beta})^2 \overline{p}(1 - \overline{p})(r+1)}{(d^{*})^2 r}$	Difference in means		
	Difference in propo	rtions: $n = \frac{(Z_{\alpha/2} + Z_{\beta})^2 \overline{p} (1 - \overline{p})(r+1)}{(d^*)^2 r}$	

Z_{β}	0.00	0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.4
-1.3	9.7	9.5	9.3	9.2	9.0	8.9	8.7	8.5	8.4	8
-1.2	11.5	11.3	11.1	10.9	10.7	10.6	10.4	10.2	10.0	9
-1.1	13.6	13.3	13.1	12.9	12.7	12.5	12.3	12.1	11.9	11
-1.0	15.9	15.6	15.4	15.2	14.9	14.7	14.5	14.2	14.0	13
-0.9	18.4	18.1	17.9	17.6	17.4	17.1	16.9	16.6	16.4	16.
-0.8	21.2	20.9	20.6	20.3	20.0	19.8	19.5	19.2	18.9	18.
-0.7	24.2	23.9	23.6	23.3	23.0	22.7	22.4	22.1	21.8	21.
-0.6	27.4	27.1	26.8	26.4	26.1	25.8	25.5	25.1	24.8	24.
-0.5	30.9	30.5	30.2	29.8	29.5	29.1	28.8	28.4	28.1	27.
-0.4	34.5	34.1	33.7	33.4	33.0	32.6	32.3	31.9	31.6	31.
-0.3	38.2	37.8	37.4	37.1	36.7	36.3	35.9	35.6	35.2	34.
-0.3	42.1	41.7	41.3	40.9	40.5	40.1	39.7	39.4	39.0	38.
-0.1	46.0	45.6	45.2	44.8	44.4	44.0	43.6	43.3	42.9	42.
-0.0	50.0	49.6	49.2	48.8	48.4	48.0	47.6	47.2	46.8	46.
0.0	50.0	50.4	50.8	51.2	51.6	52.0	52.4	52.8	53.2	53.
0.0	54.0	54.4	54.8	55.2	55.6	56.0	56.4	56.7	57.1	57.
0.1	57.9	58.9	58.7	59.1	59.5	59.9	60.3	60.6	61.0	61.
0.3	61.8	62.2	62.6	62.9	63.3	63.7	64.1	64.4	64.8	65.
0.3	65.5	65.9	66.3	66.6	67.0	67.4	67.7	68.1	68.4	68.
0.5	69.1	69.5	69.8	70.2	70.5	70.9	71.2	71.6	71.9	72.
0.5	72.6	72.9	73.2	73.6	73.9	74.2	74.5	74.9	75.2	75
0.7	75.8	76.1	76.4	76.7	77.0	77.3	77.6	77.9	78.2	78.
0.8	78.8	79.1	79.4	79.7	80.0	80.2	80.5	80.8	81.1	81.
0.9	81.6	81.9	82.1	82.4	82.6	82.9	83.1	83.4	83.6	83.
1.0	84.1	84.4	84.6	84.8	85.1	85.3	85.5	85.8	86.0	86.
1.1	86.4	86.7	86.9	87.1	87.3	87.5	87.7	87.9	88.1	88.
1.2	88.5	88.7	88.9	89.1	89.3	89.4	89.6	89.8	90.0	90
1.3	90.3	90.5	90.7	90.8	91.0	91.1	91.3	91.5	91.6	91.
1.4	91.9	92.1	92.2	92.4	92.5	92.6	92.8	92.9	93.1	93.
1.5	93.3	93.4	93.6	93.7	93.8	93.9	94.1	94.2	94.3	94
1.6	94.5	94.6	94.7	94.8	94.9	95.1	95.2	95.3	95.4	95
1.7	95.5	95.6	95.7	95.8	95.9	96.0	96.1	96.2	96.2	96.
1.8	96.4	96.5	96.6	96.6	96.7	96.8	96.9	96.9	97.0	97.
1.9	97.1	97.2	97.3	97.3	97.4	97.4	97.5	97.6	97.6	97
2.0	97.7	97.8	97.8	97.9	97.9	98.0	98.0	98.1	98.1	98
2.1	98.2	98.3	98.3	98.3	98.4	98.4	98.5	98.5	98.5	98
2.2	98.6	98.6	98.7	98.7	98.7	98.8	98.8	98.8	98.9	98
2.3	98.9	99.0	99.0	99.0	99.0	99.1	99.1	99.1	99.1	99
2.4	99.2	99.2	99.2	99.2	99.3	99.3	99.3	99.3	99.3	- 99



	Power Calculation:	Practical
p ₀ :	Proportion of exposed cont OR of importance to identi Number \circ available for stud Control - to - case ratio = 2	fy = <u>1.8</u> dy: n = <u>175</u>
p ₁ =	(0.25) x (1.8) [1+(0.25) x (1.8 - 1)]	= <u>0.375</u>
d* =	p ₁ - p ₀ = 0.375 - 0.250	= <u>0.125</u>
<u>p</u> =	$\frac{[(0.375) + (2) \times (0.25)]}{(1+2)}$	= <u>0.292</u>
Z _∂ =	$\frac{(175) \times (0.125)^2 \times (2)}{(2+1) \times 0.292 \times 0.708}^{1/2}$	- 1.96 = <u>1.01</u>

