

## THERAPY WORKSHEET

<b>Citation:</b>
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### Are the results of this single preventive or therapeutic trial valid?

Was the assignment of patients to treatments randomised? Was the randomisation list concealed?	
Was follow-up of patients sufficiently long and complete?	
Were all patients analysed in the groups to which they were randomised?	
Were patients and clinicians kept “blind” to treatment?	
Were the groups treated equally, apart from the experimental treatment?	
Were the groups similar at the start of the trial?	

### Are the valid results of this randomised trial important?

#### SAMPLE CALCULATIONS

<b>Occurrence of diabetic neuropathy at 5 years among insulin-dependent diabetics in the DCCT trial</b>		<b>Relative risk reduction (RRR)</b>	<b>Absolute risk reduction (ARR)</b>	<b>Number needed to treat (NNT)</b>
Usual insulin regimen control event rate (CER)	Intensive insulin regimen experimental event rate (EER)	$\frac{CER - EER}{CER}$	CER-EER	1/ARR
9.6%	2.8%	$\frac{9.6\% - 2.8\%}{9.6\%} = 71\%$	9.6% - 2.8% = 6.8%	1/6.8% = 15 patients
		<b>95% CI *⇒</b>	4.4% to 9.2%	11 to 23

\* **95% confidence interval (CI) on an NNT = 1/(limits on the CI of its ARR) =**

$$\pm 1.96 \sqrt{\left( \frac{CER \times (1 - CER)}{\#ofControlPts} \right) + \left( \frac{EER \times (1 - EER)}{\#ofExperPts} \right)} = \pm 1.96 \sqrt{\left( \frac{0.096 \times 0.904}{730} \right) + \left( \frac{0.028 \times 0.972}{711} \right)} = \pm 2.4\%$$

**YOUR CALCULATIONS**

		<b>Relative risk reduction (RRR)</b>	<b>Absolute risk reduction (ARR)</b>	<b>Number needed to treat (NNT)</b>
CER	EER	$\frac{CER - EER}{CER}$	CER-EER	1/ARR
		<b>95% CI ⇒</b>		

**Can you apply this valid, important evidence about therapy in caring for your patient?**

Do these results apply to your patient?	
Is your patient so different from those in the study that its results cannot apply?	
Is the treatment feasible in your setting?	
What are your patient's potential benefits and harms from the therapy?	
<i>Method I: f</i>	Risk of the outcome in your patient, relative to patients in the trial. Expressed as a decimal: _____ NNT/f = _____ / _____ = _____ (NNT for patients like yours)
<i>Method II: 1/(PEER x RRR)</i>	Your patient's expected event rate if they received the control treatment (PEER) = _____ 1/(PEERxRRR) = 1/_____ = _____ (NNT for patients like yours)
Are your patient's values and preferences satisfied by the regimen and its consequences?	
Do your patient and you have a clear assessment of their values and preferences?	
Are they met by this regimen and its consequences?	

**Additional notes:**