

## Chapter 3 Stating the Hypothesis

A hypothesis is a statement about the predicted study outcomes or an approximation of the direction of the study results. This predictive statement provides an expected answer to the research question from the investigator's point of view.

The alternative hypothesis is generally denoted as  $H_1$ , and it is a statement that suggests the outcome that the investigator may expect based on their observation or previous knowledge.  $H_1$  might be a directional or non-directional hypothesis.

The directional hypothesis is a type of hypothesis that includes a direction of the effect. For example, when comparing two drugs, we hypothesize that one of them will be superior to the other; this hypothesis is called directional hypothesis.

The non-directional hypothesis is a type of hypothesis that has no definite direction of the expected effect — for example, a cross-sectional study about the prevalence of depression among patients with renal failure.

The null hypothesis is generally denoted as  $H_0$ . It is a statement of the opposite of what an investigator predicts or expects. It is usually a statement that the relationship between the variable or the effect that the researchers are investigating does NOT exist.



### Example 1

Research Question	Do female medical students have higher depression and anxiety than males?
Alternative hypothesis	Female medical students have depression and anxiety more than male students.
Null hypothesis	Female medical students do have depression and anxiety more than male students (same or less than males)

### Example 2

Research Question	Can hand-assisted transperitoneoscopic nephrectomy be advocated over the standard laparoscopic technique for donor living kidney?
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Alternative hypothesis	hand-assisted transperitoneoscopic nephrectomy can be advocated over the standard laparoscopic technique for donor living kidney.
Null hypothesis	hand-assisted transperitoneoscopic nephrectomy can NOT be advocated over the standard laparoscopic technique for donor living kidney (NOT superior but same or less).

**Example 3**

Research Question	Is Axitinib better than Sorafenib as first-line targeted therapy for patients with metastatic renal cell carcinoma?
Alternative hypothesis	Axitinib is better than Sorafenib as first-line targeted therapy for patients with MRCC.
Null hypothesis	Axitinib is NOT better than Sorafenib as first-line targeted therapy for patients with MRCC.

**Example. 4**

In a clinical trial to test the efficacy of drug (X) for the treatment of obesity, what are the null and alternative hypotheses?



The drugs X is **not effective**

The drugs X is **effective**

## Practical Training 2

**Question 10.** Select the type of hypothesis regarding the following research question

Is droxidopa more effective than placebo for the treatment of neurogenic orthostatic hypotension?       Directional hypothesis       Non-directional hypothesis

**Question 11.** Select the type of hypothesis regarding the following research question

What is the prevalence of substantia nigra hyperechogenicity among patients with Parkinson's disease?       Directional hypothesis       Non-directional hypothesis

**Question 12.** Select the type of hypothesis regarding the following research question

Is Ketorolac better than magnesium sulphate for the management of migraine headache pain?       Directional hypothesis       Non-directional hypothesis

**Question 13.** Read the following title and determine the alternative and null hypotheses.

Bill-Axelson A, Holmberg L, Garmo H, Taari K, Busch C, Nordling S, Häggman M, Andersson SO, Andrén O, Steineck G, Adami HO. Radical prostatectomy or watchful waiting in prostate cancer—29-year follow-up. *New England Journal of Medicine*. 2018 Dec 13;379(24):2319-29.

Alternative Hypothesis	Radical prostatectomy is better than watchful waiting for patients with localized prostate cancer
Null Hypothesis	Radical prostatectomy has equal benefit/harm as watchful waiting for patients with localized prostate cancer Watchful waiting is better than radical prostatectomy is for patients with localized prostate cancer

**Question 14.** Read the following title and determine the alternative and null hypothesis.

Rutledge T, Atkinson JH, Chircop-Rollick T, D'Andrea J, Garfin S, Patel S, Penzien DB, Wallace M, Weickgenant AL, Slater M. Randomized controlled trial of telephone-delivered cognitive-behavioral therapy versus supportive care for chronic back pain. *The Clinical journal of pain*. 2018 Apr 1;34(4):322-7.

Alternative Hypothesis	Telephone-delivered cognitive behavioral therapy is better than supportive care for chronic back pain
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Null Hypothesis	Telephone-delivered cognitive behavioral therapy has equal benefit/harm as supportive care for chronic back pain  Supportive care is better than Telephone-delivered cognitive behavioral therapy for chronic back pain
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**Question 15.** Read the following title and determine the alternative and null hypothesis.

Strand-Holm KM, Fuglsang J, Ovesen PG, Maimburg RD. Diabetes Mellitus and lower genital tract tears after vaginal birth: A cohort study. Midwifery. 2019 Feb.

Alternative Hypothesis	Women with diabetes Mellitus have an increased risk of lower genital tract tears after vaginal birth
Null Hypothesis	Women with diabetes Mellitus <b>do NOT</b> have an increased risk of lower genital tract tears after vaginal birth compared to non-diabetics  Women with diabetes Mellitus have a similar risk of lower genital tract tears after vaginal birth compared to non-diabetics  Women with diabetes Mellitus have less risk of lower genital tract tears after vaginal birth compared to non-diabetics

**Question 16.** Read the following title and determine the alternative and null hypothesis.

Barzilay R, Calkins ME, Moore TM, Wolf DH, Satterthwaite TD, Scott JC, Jones JD, Benton TD, Gur RC, Gur RE. Association between traumatic stress load, psychopathology, and cognition in the Philadelphia Neurodevelopmental Cohort. Psychological medicine. 2019 Jan;49(2):325-34.

Alternative Hypothesis	There is an association between traumatic stress load, psychopathology, and cognition in the Philadelphia Neurodevelopmental Cohort
Null Hypothesis	There is no association between traumatic stress load, psychopathology, and cognition in the Philadelphia Neurodevelopmental Cohort

**Question 17.** Read the following title and determine the alternative and null hypothesis if the outcome measure is the overall survival after 10 years

Bill-Axelson A, Holmberg L, Garmo H, Taari K, Busch C, Nordling S, Häggman M, Andersson SO, Andrén O, Steineck G, Adami HO. Radical prostatectomy or watchful waiting in prostate cancer—29-year follow-up. *New England Journal of Medicine*. 2018 Dec 13;379(24):2319-29.

Alternative Hypothesis	Patients with localized prostate cancer undergoing radical prostatectomy have higher 10-year survival than those with watchful waiting
Null Hypothesis	Patients with localized prostate cancer undergoing radical prostatectomy have the same 10-year survival rate as those with watchful waiting
	Patients with localized prostate cancer undergoing radical prostatectomy have less 10-year survival rate than those with watchful waiting

**Question 18.** Read the following title and determine the alternative and null hypothesis if the outcome is the improvement in pain score measured by the VAS

Rutledge T, Atkinson JH, Chircop-Rollick T, D'Andrea J, Garfin S, Patel S, Penzien DB, Wallace M, Weickgenant AL, Slater M. Randomized controlled trial of telephone-delivered cognitive-behavioral therapy versus supportive care for chronic back pain. *The Clinical journal of pain*. 2018 Apr 1;34(4):322-7.

Alternative Hypothesis	Patient with chronic back pain who receive telephone-delivered cognitive-behavioral therapy have more improvement in the VAS pain scores than those with supportive care
Null Hypothesis	Patient with chronic back pain who receive telephone-delivered cognitive-behavioral therapy have the same improvement in VAS pain scores as those with supportive care
	Patient with chronic back pain who receive telephone-delivered cognitive behavioral therapy have less improvement in VAS pain scores as those with supportive care

**Question 19.** Read the following title and determine the alternative and null hypothesis assuming that the outcome is expressed as the odds of having genital tract injury between diabetic vs. non-diabetic women

Strand-Holm KM, Fuglsang J, Ovesen PG, Maimburg RD. Diabetes Mellitus and lower genital tract tears after vaginal birth: A cohort study. *Midwifery*. 2019 Feb.

Alternative Hypothesis	Diabetic women have higher odds of genital tract injury compared to those non-diabetic women
Null Hypothesis	Diabetic women have the same odds of genital tract injury as non-diabetic women  Diabetic women have lower odds of genital tract injury compared to those non-diabetic women

**Question 20.** Read the following title and determine the alternative and null hypothesis if the outcome measure is the overall Survival after 10 years the outcome is expressed as the statistical effect size, Hazard Ratio

Bill-Axelson A, Holmberg L, Garmo H, Taari K, Busch C, Nordling S, Häggman M, Andersson SO, Andrén O, Steineck G, Adami HO. Radical prostatectomy or watchful waiting in prostate cancer—29-year follow-up. *New England Journal of Medicine*. 2018 Dec 13;379(24):2319-29.

H1	Hazard Ratio=Survival in experimental control/Survival in the control group # If radical prostatectomy is better than watchful waiting Then $HR > 1$
Ho	$HR = 1$ $HR < 1$

Note that if the outcome is undesirable (i.e., mortality rate), then H1 will be  $HR < 1$  and H0 will be  $HR \geq 1$ .

**Question 21.** Read the following title and determine the alternative and null hypothesis if the outcome is the improvement in pain score measured by the VAS and expressed as the statistical effect size, mean difference.

Rutledge T, Atkinson JH, Chircop-Rollick T, D'Andrea J, Garfin S, Patel S, Penzien DB, Wallace M, Weickgenant AL, Slater M. Randomized controlled trial of telephone-delivered cognitive-behavioral therapy versus supportive care for chronic back pain. *The Clinical journal of pain*. 2018 Apr 1;34(4):322-7.

H1	Mean Difference = improvement in Experimental – improvement in the control group. If telephone-delivered cognitive behavioral therapy achieves more improvement in the VAS pain scores than supportive care Then $MD < 0$
Ho	$MD = 0$ $MD > 0$

Note that in this example, a higher VAS score indicates more pain severity, while lower scores indicate less pain. Therefore, the improvement in pain is represented in negative

values. If the score is in the opposite direction (i.e., more patient satisfaction with higher values), then  $H_1$  will be  $MD > 0$ , and  $H_0$  will be  $MD \leq 0$ .

**Question 22.** Suggest a research question (whose hypothesis is directional)

Research question 1	
$H_1$	
$H_0$	

**Question 23.** Suggest a research question (whose hypothesis is directional)

Research question 1	
Outcome measure	
Effect size	
$H_1$	
$H_0$	

**Question 24.** Suggest a research question (whose hypothesis is directional)

Research question 1	
Outcome measure	
Effect size	
$H_1$	
$H_0$	