# Chapter 3 **Stating the Hypothesis**

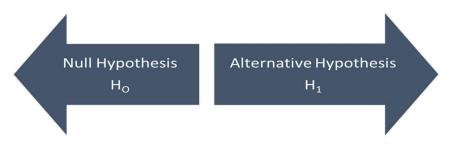
A hypothesis is a statement about the predicted study outcomes or an approximation of the direction of the study results. This predictive statement provides an expected answer to the research question from the investigator's point of view.

The alternative hypothesis is generally denoted as H1, and it is a statement that suggests the outcome that the investigator may expect based on their observation or previous knowledge. H1 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-sectionals study about the prevalence of depression among patients with renal failure.

The null hypothesis is generally denoted as H0. 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.

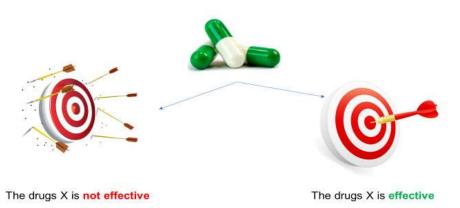


Example 1	
Research Question	Do female medical students have higher depression and anxiety than males?
Alternative hypothesis	Female medical students have depression and anxiety more than male students.
Null hypothesis	Female medical students do have depression and anxiety more than male students (same or less than males)
Example 2	
Research Question	Can hand-assisted transperitoneoscopic nephrectomy be advocated over the standard laparoscopic technique for donor living kidney?

Negida's Handbook of Medical Research Ahmed Negida, MBBCh		
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?



## **Practical Training 2**

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

Is droxidopa more e	ffective than placebo for the t	reatment of neurogenic orthostatic
hypotension?	☐ Directional hypothesis	$\square$ Non-directional hypothesis

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

What is the prevalence of substantia nigra hy	yperechogenicity 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	$\square$ 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	Radical prostatectomy is better than watchful waiting for patients
Hypothesis	with localized prostate cancer
Null	Radical prostatectomy has equal benefit/harm as watchful waiting for patients with localized prostate cancer
Hypothesis	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	Telephone-delivered cognitive behavioral therapy is better	
Hypothesis	than supportive care for chronic back pain	

#### Negida's Handbook of Medical Research Ahmed Negida, MBBCh

Ni. II I I I I I I I I I I I I I I I I I	Telephone-delivered cognitive behavioral therapy has equal benefit/harm as supportive care for chronic back pain
Null Hypothesis	Supportive care is better than Telephone-delivered cognitive behavioral therapy for chronic back pain

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

#### Negida's Handbook of Medical Research Ahme

#### Ahmed Negida, MBBCh

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.

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

#### Negida's Handbook of Medical Research Ahmed Negida, MBBCh

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

## **Negida's Handbook of Medical Research**

## **Ahmed Negida, MBBCh**

values. If the score is in the opposite direction (i.e., more patient satisfaction with higher values), then H1 will be MD>0, and H0 will be MD  $\leq$ 0.

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

Research question 1	
H1	
H <sub>0</sub>	

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

Research question 1	
Outcome measure	
Effect size	
H1	
Н0	

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

Research question 1	
Outcome measure	
Effect size	
H1	
H0	