

# *Depression & Multiple Sclerosis*

**Research Example**

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# Example - Outline

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- \* **Hypotheses**
- \* **Study Design**
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- \* **Sample Size & Power**
- \* **Non-Normal vs. Normal Distribution**
- \* **Results**
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  - \* Discussion
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# Background

- \* Major depressive disorders and suicide are highly common in MS
- \* Despite the high prevalence, only half of patients are screened
- \* Depression and Suicide ideation often remain undetected



Vincent Van Gogh's 1890 painting  
"At Eternity Gate"

# Depression & Multiple Sclerosis

- \* MS is a progressive inflammatory disease
- \* Depression is a chronic disease
- \* Upregulation of pro-inflammatory cytokines
- \* Questionable relationship between depression & progression of MS
- \* Studies have shown conflicting results regarding the relationship between depression and progression of disease
- \* Cause & effect relationship is questionable
- \* Chicken-Egg phenomenon:

\* Depression ↔ MS

# The magnitude of Depression & Suicide in MS

- \* **The lifetime prevalence of major depression among individuals with MS is 50%**
- \* **Untreated depression can lead to**
  - \* **1) Immune dysregulation associated with MS**
  - \* **2) Significant social and functional impairments**
  - \* **3) Suicide - 7.5 times higher than in the general population**

# Research Question?

- \* **Define the question simply and clearly identify the dependent variable (outcome) and the independent variables (variables leading to the outcome)**
- \* **What is the relationship between Depression & MS as measured by the Expanded Disability Status Scale and relapse rate?**
- \* **May add other variables – MRI disease or others for example Optic Coherence Tomography (OCT)**

# Study Hypotheses

## \* Null Hypothesis

- \* There is no relationship between depression & MS
- \* There is no difference between the BDI-II and the BDI-FS

## \* Alternate Hypotheses

- \* There is positive or negative relationship between depression and MS
- \* People who had low or high level of depression as measured by the BDI will have different MS disease based on the EDSS and relapse rate
- \* There is a difference between the BDI-II and BDI-FS in identifying depression

# Conceptual Framework: Behavioral-cognitive Theory

- \* **Major life stressors can result in depressive disorders**
- \* **Mobilization of support from family and support networks may result in a negative feedback and reinforcement of a depressive behavior**
- \* **Depression is mediated by environmental stimuli and by the individuals' attendance to stimuli**
- \* **Biological/organic etiology for depression**

Davidson et al., 2004; Lovejoy & Matteis, 1997

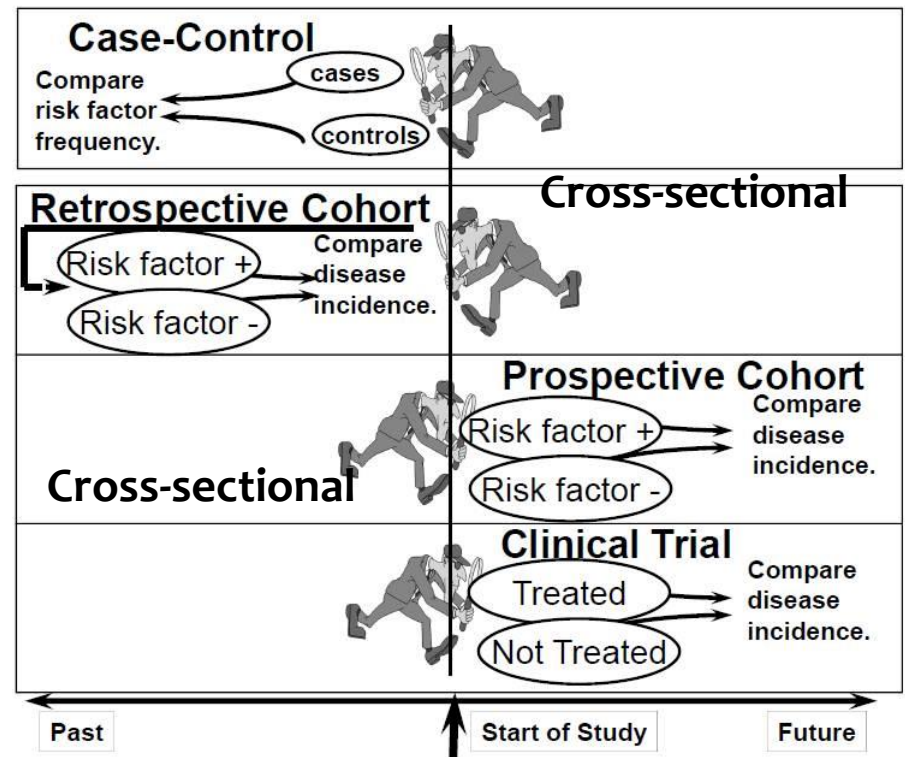


# Study Design

- \* **Correlational descriptive**
- \* **Cross-sectional study**
  - \* **Assessing BDI-II & BDI-FS, EDSS & Relapse rate once during the study**
  - \* **One point assessment**
- \* **Dependent Variable**
  - \* **MS disease level**
    - \* **EDSS (Ordinal Scale & as categorical)**
    - \* **Number of Relapses**
- \* **Independent Variable**
  - \* **Depression (BDI)**
    - \* **Numerical**
    - \* **Categorical**

# Methods

- \* Cross-sectional study
- \* Convenience sample
- \* Small sample size n=34
- \* Statistical methods
  - \* Descriptive statistics
  - \* Spearman correlation
  - \* Logistic regression



# Instruments

- \* Beck Depression Inventory – II (BDI-II)
- \* Beck Depression Fast Screen (BDI-FS)
- \* Expanded Disability Status Scale (EDSS)
- \* Number of Relapses based on chart review and demographic sheet data

# The Beck Depression Inventory (BDI)

## \* Sadness

- \* 0. I do not feel sad.
- \* 1. I feel sad much of the time.
- \* 2. I am sad all the time.
- \* 3. I am so sad or unhappy that I can't stand it.

## \* Suicidal Thoughts or Wishes

- \* 0. I don't have any thoughts of killing myself.
- \* 1. I have thoughts of killing myself, but I would not carry them out.
- \* 2. I would like to kill myself.
- \* 3. I would kill myself if I had the chance.

# Collection of Data

- \* **Consent form**
- \* **One point data collection**
- \* **One follow up visit**
- \* **Input data into SPSS**
- \* **All patients data collected from one large MS Center**

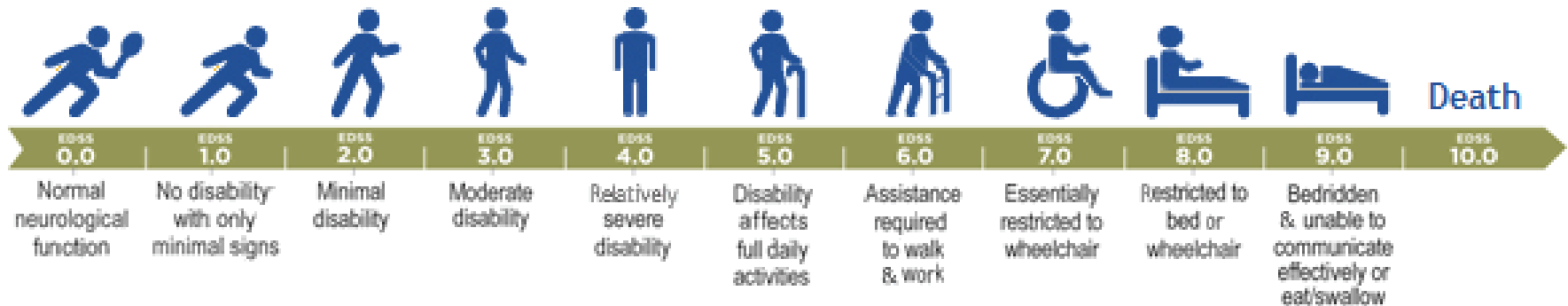


# Definition of Variables

- \* **EDSS** = EDSS $\leq$ 4 - Mild & moderate disability
  - \* EDSS change by 1 point on the scale
- \* **Relapse** = Number of relapses (acute attacks)
- \* **BDI** = Depression measured by the Beck depression Inventory
  - \* BDI as categorical variable
    - \* BDI-II - + depression  $\geq$  14
    - \* BDI-FS - +depression  $\geq$  4
  - \* BDI as ordinal variable

# Expanded Disability Status Scale (EDSS)

## The Expanded Disability Status Scale (EDSS)



**EDSS  $\leq 4$  = Ambulatory; Mild to moderate disability**

**EDSS  $> 4$  = Increased disability requiring assistive device to walk or wheelchair**





# Other Independent Variables

- \* **Age**
- \* **Gender**
- \* **Ethnicity/race**
- \* **Education level**
- \* **Work**
- \* **Marital status**
- \* **Living alone or with others**



- \* **Type of MS**
- \* **Type of DMT**
- \* **Smoking**
- \* **Alcohol**
- \* **Vitamin D**



# Sample Size & Power

- \* A Power level chosen is 80%
- \* A level of significance of 0.05
- \* Distribution & type of variables
- \* G-Power software (free download) helps you to calculate sample size
- \* <http://www.gpower.hhu.de/>

Questions:  
How large should  
my sample be?

Answer:  
It depends...

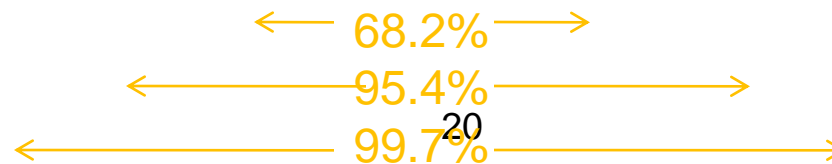
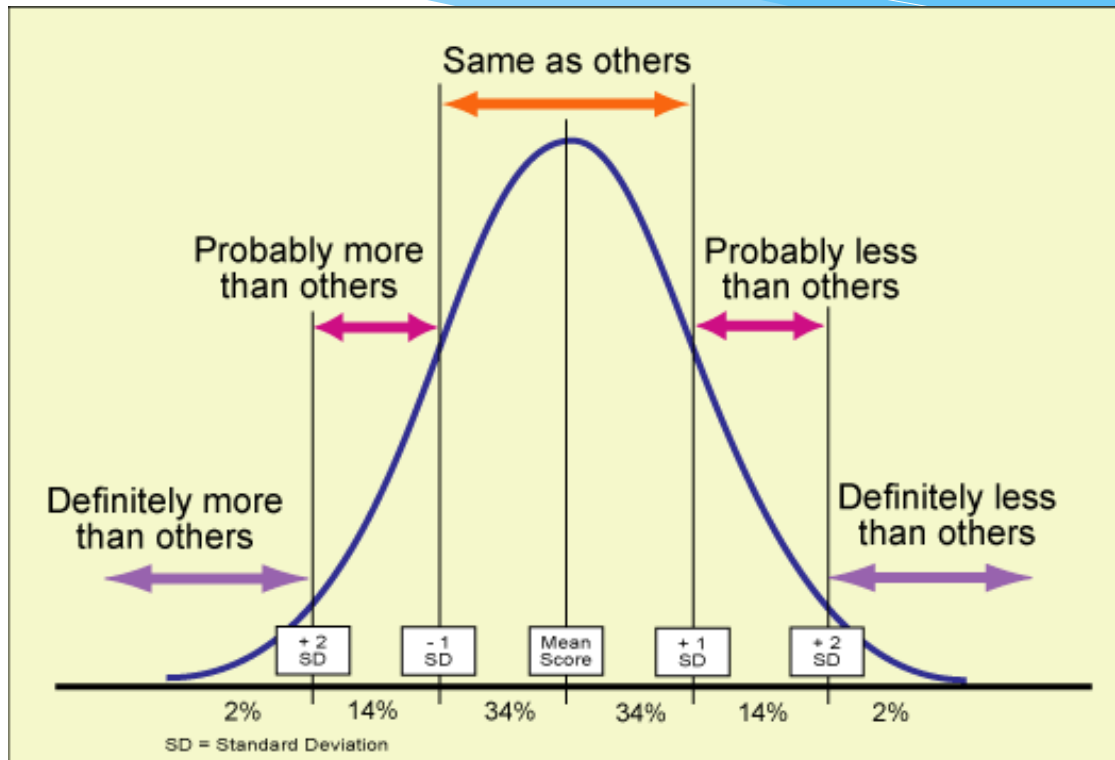
*...large enough to be an accurate  
representation of the population*  
*...large enough to achieve  
statistically significant results*



# Normal Distribution

- \* Normal distribution – the variable parameters are around the mean for example +2 and -2 from the standard deviation
- \* Standard deviation – the distance of the result from the mean for example the BDI value of all the participants around the mean or a very heterogenic group
- \* You need to check the distribution of your results before deciding upon statistical tests to use in your study

# Normal Distribution



# Statistical analysis

- \* Think about the appropriate statistical tests for the distribution
  - \* Normal distribution – comparing between the mean of different groups – Parametric tests: ANOVA, ANCOVA, T test, Regression
  - \* Non-Normal distribution – comparing between the median of different groups – Non Parametric tests: Kruskal Wallis, Mann-Whitney, Chi Square, Regression

# Statistical Analysis

- \* Think about the appropriate statistical tests for the different type variables
- \* Interval or Ratio variables – Pearson correlation
- \* Ordinal & interval variables – Spearman correlation
- \* Categorical 2 x 2 table – Chi Square analysis
- \* Multi-categorical – Kruskal Wallis & Mann-Whitney
- \* Categorical variables – Logistic regression for dependent categorical variable – dichotomous or multinomial

## Results: Sample Demographics

- \* **N = 34 subjects with MS (85% RRMS)**
- \* **Mean age 41.6 (SD – 12.5, R = 19-74)**
- \* **88.3% had college or postgraduate education**  
**Mean yrs education 16.7 (SD – 2.8, R = 10-23)**
- \* **70.6% Female**
- \* **73.5% Caucasian**
- \* **67.6 % Married or lived with partner or family**
- \* **70.6% worked full time**

# Results: Depression Prevalence

- \* There was a significant positive correlation between the BDI-II and BDI-FS ( $r = .82, p = .01$ )
- \* The prevalence of depression as assessed by the Beck Depression Inventory-II (BDI-II) was 15% with two subjects identified as having major depression, compared to 21% as measured by the Beck Depression Inventory Fast-Screen (BDI-FS) with three subjects identified as having major depression



# Results: Correlation between Depression & Disability/Relapses

- \* The BDI-FS identified significantly more depressed persons than the BDI-II ( $X^2 = 22.61$ ,  $df = 1$ ,  $p < .001$ )
- \* There was no correlation between the extent of disability or number of MS relapses and depression as measured by either the BDI-II or BDI-FS
- \* The study supports the ability of both tools to identify depressive symptoms among individuals with MS

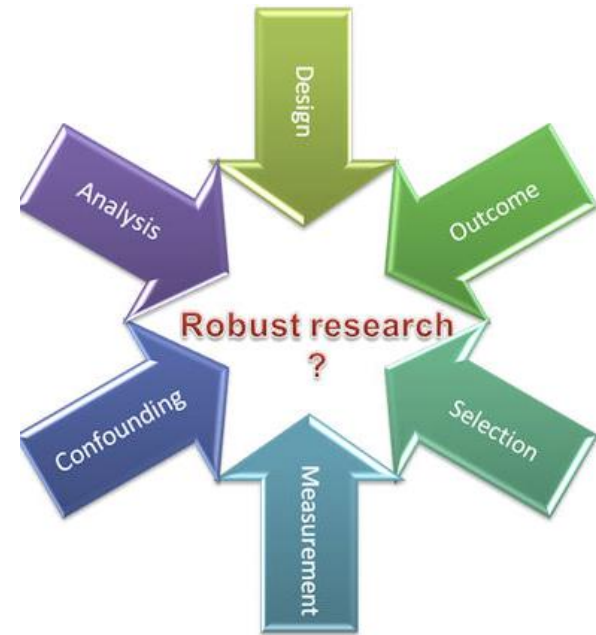
# Strengths of the Study

- \* **Multiple variables / confounders**
- \* **Different statistical analyses**
- \* **Sample size**
- \* **Similar demographic characteristics as the general MS population**
- \* **Potential generalizability of the study**
- \* **Basis for future study – Prospective Cohort**



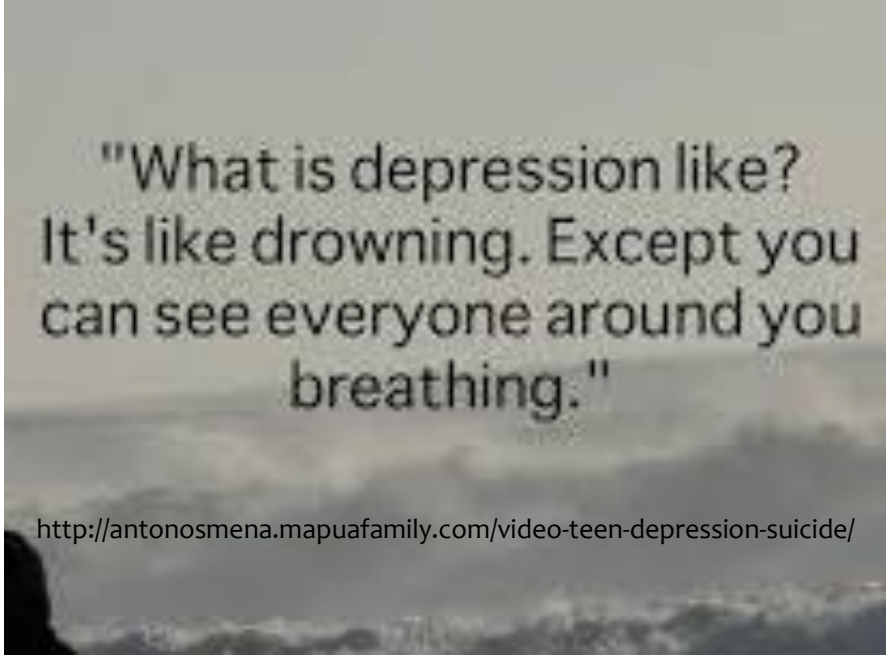
# Limitations of the Study

- \* **Cross-sectional study**
- \* **The EDSS calculation is based on one point of study**
- \* **Selection bias of participants**
- \* **Onset of disease not correlated with BDI testing but may control for duration of disease**



# Conclusions

- \* Depression, appetite changes, sadness and loss of pleasure are determinants of suicide in MS
- \* Early screening is critical in clinical practice
- \* Larger studies are warranted to show the associations



"What is depression like?  
It's like drowning. Except you  
can see everyone around you  
breathing."

<http://antonosmena.mapuafamily.com/video-teen-depression-suicide/>

# Thank You!



Cats are natural  
Antidepressants

Lucy & Max

Side effects:  
chewed  
furniture,  
allergies,  
sleepless nights,  
scratches, and  
furry house

# Thank You!