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Presentation of clinical epidemiology study result

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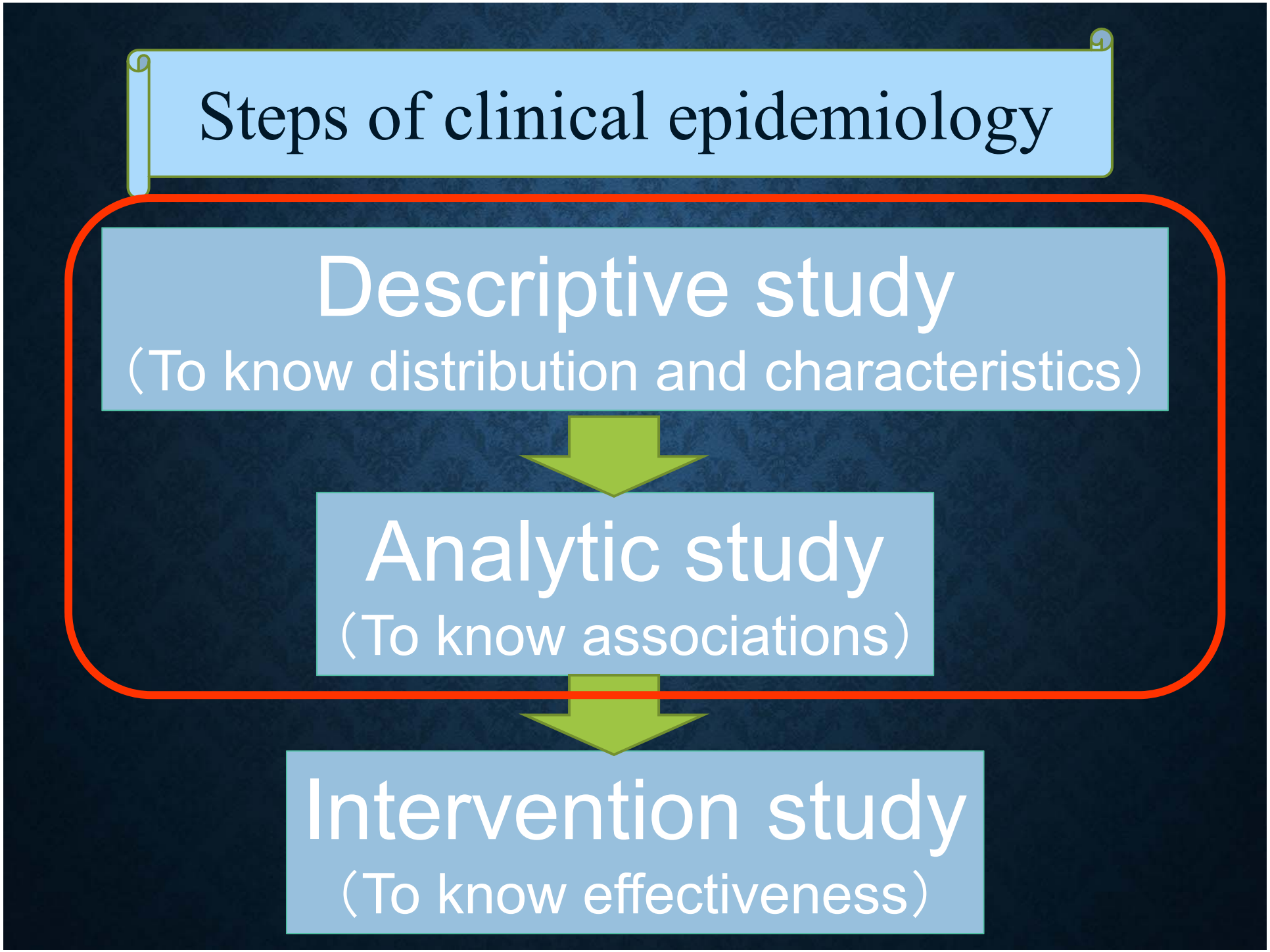

Steps of clinical epidemiology
Descriptive study
（To know distribution and characteristics）
Analytic study
（To know associations）
Intervention study
（To know effectiveness）

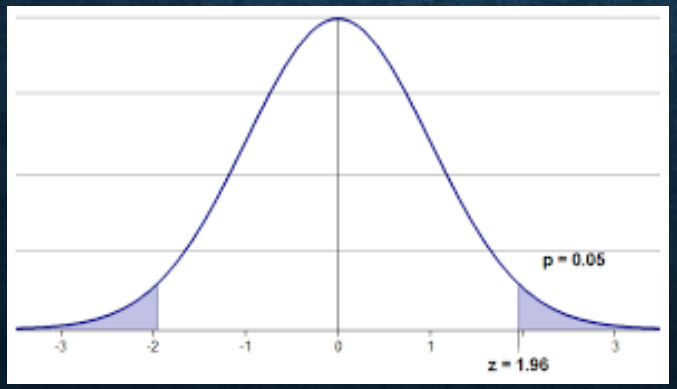
Descriptive study

- **Checking distribution and characteristics of the participants**: To know the distribution and characteristics may lead adequate advanced analysis.
- **Checking errors:** Data errors may be corrected before main analysis.

Analytic study

- **Estimating associations**: To know associations between outcome and factors.
- **Exploring associated factors:** To explore factors associated with outcome.

Important reminder to interpret the statistical significance.



Systolic BP (mmHg) in A and B group

No		SBP		SBP
1	A	108	B	112
2	A	119	B	141
3	A	116	B	105
4	A	103	B	125
5	A	132	B	101
6	A	97	B	126
7	A	111	B	130
8	A	114	B	143
9	A	124	B	115
10	A	124	B	94
11	A	114	B	93
12	A	118	B	117
13	A	127	B	99
14	A	125	B	108
15	A	136	B	135
16	A	120	B	108
17	A	94	B	119
18	A	105	B	135
19	A	108	B	119
20	A	115	B	135
21	A	135	B	131
22	A	114	B	128
23	A	130	B	95
24	A	134	B	152
25	A	121	B	120
26	A	97	B	114
27	A	129	B	136
28	A	135	B	162
29	A	124	B	140
30	A	136	B	121

Group	N	Mean SBP	SD
A	30	118.833	12.228
B	30	121.967	17.4207
		P value=**0.4233**	

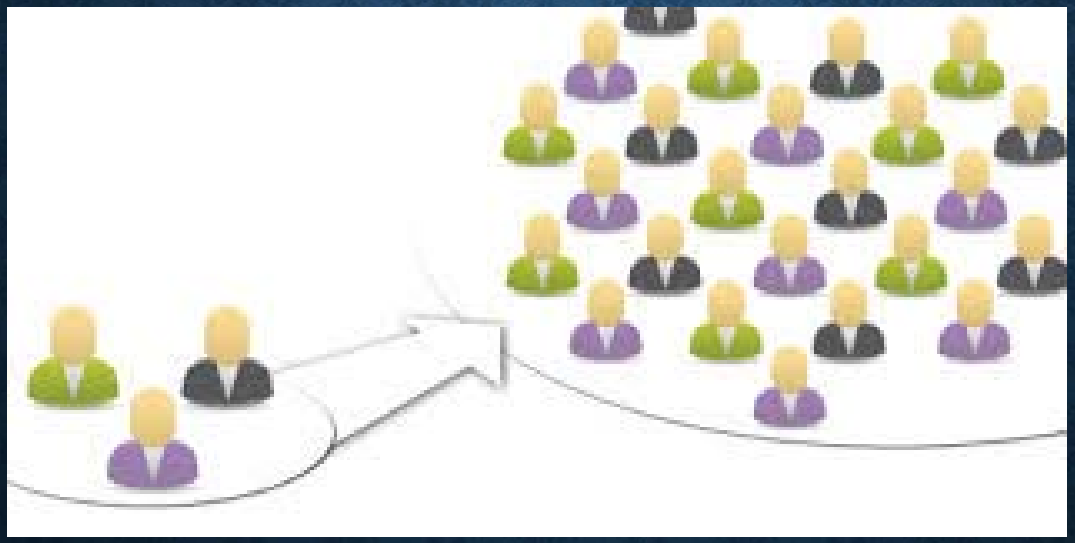
No statistical significance is observed, if we analyze 30 subjects in each group.

Sample size is increased from 30 to 510 by 17 times

Group	N	Mean SBP	SD
A	510	118.833	12.0342
B	510	121.967	17.1447
		P value=**0.0008**	

Statistical significance is observed, although mean SBP are not changed..

It is possible to observe statistical significance with a large sample size while no statistical significance is observed with a smaller sample size.



Explorable.com

Which do you think is true?

Which do you think is true: statistical significance with a large sample size or no statistical significance with a small sample size?

A statistical significance may be observed with a large sample size although there is less clinical significance.

A statistical significance may not be observed with a small sample size although there is actual clinical significance.

Be careful when you interpret your results!

An example of research question

Your BMI is over than 30. You have to reduce your body weight !

My body style Is very thin!

No need Intervention.

What is "BMI"?

What has happened? The patient has diabetes which is treated based on HbA1c.

Diabetes Control among Vietnamese Patients in Ho Chi Minh City: An Observational Cross-Sectional Study

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Amary

Evaluation of diabetic control

Evaluation	Excellent	Good	Fair	poor
HbA1c（%）	6.0	6.1 ～6.9	7.0 ～7.9	8.0 ～

Table 2. Distribution of Hemoglobin A1c among Vietnamese Diabetic Patients

Ranges of Hemoglobin A1c (%)[a)]	N (%)	
	People Hospital 115 N=223	Medic Center N=383
5.7 or less	15 (6.7)	13 (3.3)
5.8-6.4	38 (17.0)	64 (16.7)
6.5-6.9	33 (14.8)	72 (18.8)
7.0-7.9	47 (21.1)	103 (26.9)
8.0 or over	90 (40.4)	131 (34.2)

a) Hemoglobin A1c was stratified according to the Diabetes Mellitus Treatment Guideline established by the Japan Diabetes Association.

Table 3. Perception of Good Diabetic Control among Diabetic Patients

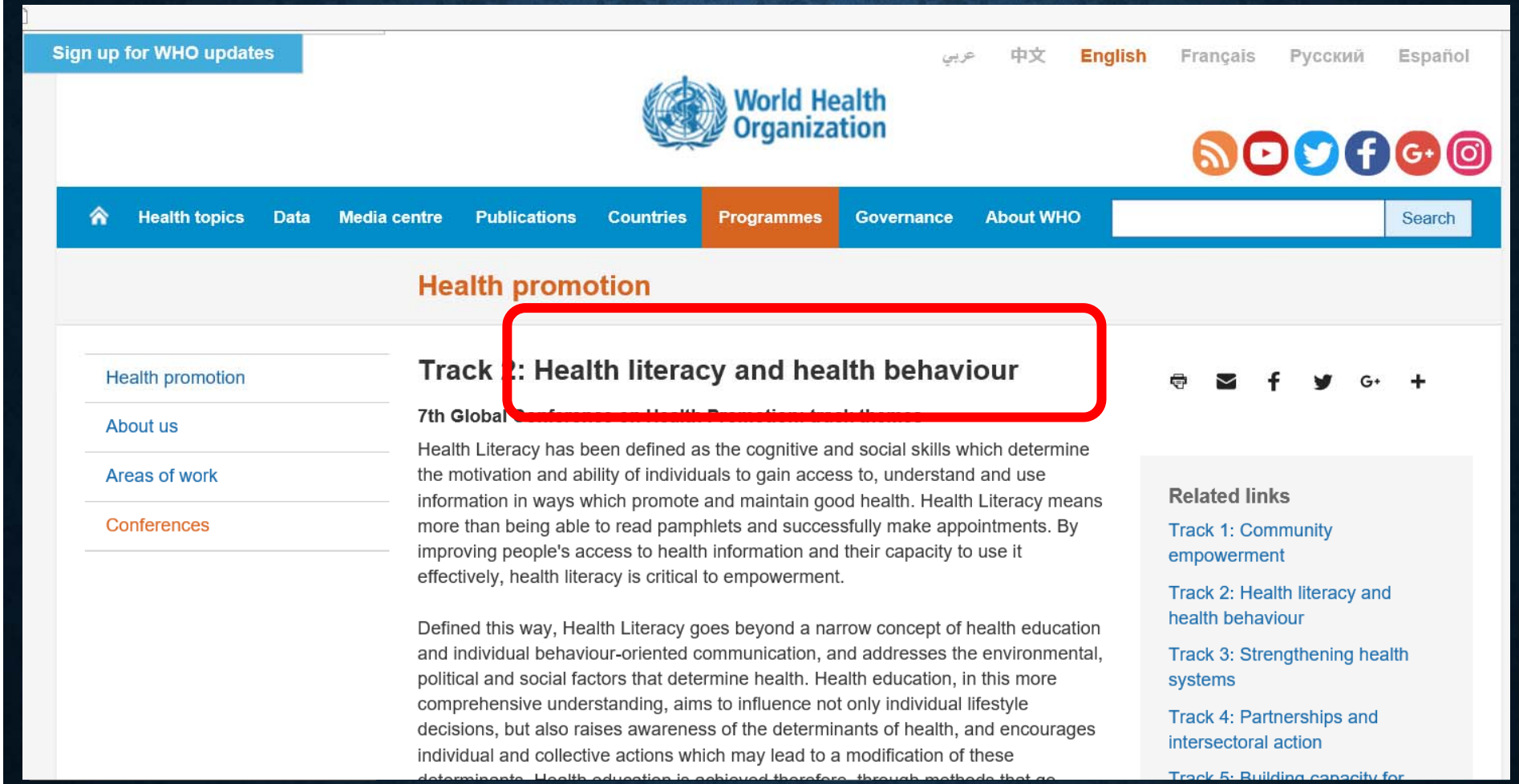
Ranges of Hemoglobin A1c(%)[b]	Perception of good diabetic control [N (%)][a]	
	People Hospital 115 N=222	Medic Center N=384
5.7 or less	12/15 (80.0)	10/13 (76.9)
5.8-6.4	37/42 (88.1)	67/81 (82.7)
6.5-6.9	28/35 (80.0)	47/68 (69.1)
7.0-7.9	32/44 (72.7)	66/95 (69.5)
8.0 or over	47/86 (54.7)	57/127 (44.9)

a) Perception of good diabetic control was estimated by 3 or 4 from 4 point scales (Not at all=1, to a great extent=4).
b) Hemoglobin A1c was stratified according to the Diabetes Mellitus Treatment Guideline established by the Japan Diabetes Association.

A research question

About half of the patients whose diabetic control was poor (HbA1c ≧8.0 %), had good diabetic control perception .

We have to consider “Patient’ s ability to promote their health”.



http://www.who.int/healthpromotion/conferences/7gchp/track2/en/

Definition of Health Literacy

Health Literacy has been defined as the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health.

Simple questionnaire to assess Health Literacy

1	Seeking information from various sources
2	Extracting relevant information
3	Understanding and communicating the information
4	Considering the credibility of the information
5	Making decisions based on the information

Ishikawa H, Nomura K, Sato M, Yano E. Health Promot Int. 2008; 23: 269-274.

How to present distribution and characteristics?

- **The first Table (Table 1) usually shows distribution and characteristics.**

- **As representative values, mean (standard deviation) for parametric data, median (minimum, maximum) for non-parametric data, percentage for categorical data are usually used.**

Table 1. Health literacy specific characteristics among men (N=781)

	Mean (±SD) or N (%)		
	Low health literacy (≤13) (N=350)	High health literacy (≥14) (N=431)	P[a)]
Age (years)	51.2 (9.9)	51.0 (9.9)	
Anthropometric measurements			
Height (cm)	170.0 (6.5)	170.2 (6.4)	
Body weight (kg)	68.6 (12.1)	68.8 (11.1)	
Body mass index (BMI)	23.7 (3.8)	23.7 (3.4)	
Waist circumference (cm)	85.0 (9.5)	84.6 (8.8)	
Atherosclerotic complications			
Cardiovascular disease	13 (3.7)	18 (4.2)	
Cerebrovascular disease	3 (0.9)	8 (1.9)	
Hypertension-related factors			
Systolic blood pressure (mmHg)	133.5 (19.4)	135.0 (17.7)	
Diastolic blood pressure (mmHg)	81.1 (12.4)	81.7 (12.1)	
Antihypertensive drug use (yes)	72 (20.6)	102 (23.7)	

Mean (standard deviation) is used for continuous variables

Number (percentage) is used for categorical variables

Healthy lifestyle characteristics					
Alcohol consumption (non-everyday drinker)	161	(46.0)	223	(51.7)	
Smoking behavior (non-current smoker)	174	(49.7)	262	(60.8)	**
Exercise frequency (2 times or more per week)	48	(13.7)	96	(22.3)	**
Body mass index (18.5-24.9)	216	(61.7)	293	(68.0)	*
Sleep hours (6-9)	220	(62.9)	290	(67.3)	
Breakfast (every morning)	277	(79.1)	355	(82.4)	
Snack between meals (no)	287	(82.0)	371	(86.1)	
Total number of healthy lifestyle items	4.0	(1.2)	4.4	(1.2)	**
Proportion of participants with 6 or 7 total number of healthy lifestyle items	34	(9.7)	76	(17.6)	**

As for presentation of “P value”, asterisk mark is sometimes used (*P<0.05, **P<0.01). Direct input also may be applicable.

1. Check the distribution of age, body mass index, waist circumference. (Draw histograms)
2. Estimate representative value. (mean, standard deviation)
3. Estimate statistical difference of age, BMI and WC between low and high health literacy. (t-test or U-test)
4. Estimate statistical difference of cardiovascular and cerebrovascular disease. (Chi square test)

How to present analytic study data?

Which statistical methods do you use?

- Linear regression analysis
- Logistic regression analysis
- Correlation analysis

Table 2. Logistic regression analysis of health literacy for men with 6-7 healthy lifestyle characteristics (N=781)

	Univariate analysis			Multivariate analysis					
				Model 1			Model 2		
	OR[a]	95% CI[b]	P[e]	OR[a]	95% CI[b]	P[e]	OR[a]	95% CI[b]	P[e]
Health literacy									
Seeking information from various sources (≥4 vs. <4)	1.26	0.78-2.02		-	-		1.44	0.89-2.34	
Extracting relevant information (≥4 vs. <4)	1.31	0.85-2.01		-	-		1.50	0.97-2.32	
Understanding and communicating the information (≥4 vs. <4)	1.59	1.06-2.39	**	-	-		1.63	1.08-2.47	*
Considering the credibility of the information (≥4 vs. <4)	1.49	0.99-2.23		-	-		1.39	0.92-2.10	
Making decisions based on the information (≥4 vs. <4))	2.16	1.42-3.27	**	-	-		2.04	1.34-3.10	**
Total score (≥14 vs. <14)	**1.99**	**1.29-3.06**	**	**2.08**	**1.33-3.23**	**	-	-	

Order; Univariate analysis, Multivariate analysis

Number (%), Odds ratio, 95% confidence interval, and P value

Estimate the potential of high HL to promote a healthy lifestyle with 6-7 healthy characteristics or presence of metabolic syndrome. (Logistic regression analysis)

1. Univariate analysis
2. Multivariate analysis adjusting with age (years), and atherosclerotic complications (cardiovascular and cerebrovascular diseases)

Implication of multivariate analysis (Example)

		Univariate analysis			Model 1[c]			Model 2[d]		
	N (%)	OR[a]	95% CI[b]	*P*	OR[a]	95% CI[b]	*P*	OR[a]	95% CI[b]	*P*
Age (years)[e]		1.87	1.71-2.04	**	1.98	1.81-2.17	**	1.85	1.68-2.04	**
Anthropometric measurements										
Body mass index (BMI)										
C1 < 25.0	3990 (72.2)	Reference			Reference					
25.0 ≤ C2 < 27.5	1040 (18.8)	2.11	1.71-2.60	**	2.10	1.72-2.56	**			
27.5 ≤ C3 < 30.0	331 (6.0)	2.25	1.63-3.10	**	2.37	1.75-3.23	**			
30.0 ≤ C4	166 (3.0)	2.67	1.76-4.06	**	3.46	2.34-5.12	**			
Waist circumference (cm)			-							
C1 < 85	2614 (47.3)	Reference						Reference		
85 ≤ C2 < 90	1419 (25.7)	1.51	1.20-1.90	**				1.40	1.10-1.78	**
90 ≤ C3 < 95	833 (15.1)	1.73	1.14-2.25	**				1.55	1.17-2.03	**
95 ≤ C4	661 (12.0)	2.65	2.06-3.41	**				2.51	1.92-3.30	**

C4 was 3.46 times likely to have low % vital capacity (<80%) compared to reference (C1) after adjusting by cofounders.

Table 2. Logistic regression analysis of health literacy for men with 6-7 healthy lifestyle characteristics (N=781)

	Univariate analysis			Multivariate analysis					
				Model 1			**Model 2**		
	OR[a]	95% CI[b]	P[e]	OR[a]	95% CI[b]	P[e]	OR[a]	95% CI[b]	**P[e]**
Health literacy									
Seeking information from various sources (≥4 vs. <4)	1.26	0.78-2.02		-	-		1.44	0.89-2.34	
Extracting relevant information (≥4 vs. <4)	1.31	0.85-2.01		-	-		1.50	0.97-2.32	
Understanding and communicating the information (≥4 vs. <4)	1.59	1.06-2.39	**	-	-		1.63	1.08-2.47	*
Considering the credibility of the information (≥4 vs. <4)	1.49	0.99-2.23		-	-		1.39	0.92-2.10	
Making decisions based on the information (≥4 vs. <4))	2.16	1.42-3.27	**	-	-		2.04	1.34-3.10	**
Total score (≥14 vs. <14)	**1.99**	**1.29-3.06**	**	**2.08**	**1.33-3.23**	**	-	-	

Interpret the result of OR

https://kdhhealthcomm.wordpress.com/category/health-literacy-3/

Yokokawa *et al. Diabetol Metab Syndr (2016) 8:30*
DOI 10.1186/s13098-016-0142-8

Diabetology &
Metabolic Syndrome

RESEARCH Open Access

Association between health literacy and metabolic syndrome or healthy lifestyle characteristics among community-dwelling Japanese people

Hirohide Yokokawa[1*], Hiroshi Fukuda[1], Motoyuki Yuasa[2], Hironobu Sanada[3,4], Teruhiko Hisaoka[1] and Toshio Naito[1]

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https://dmsjournal.biomedcentral.com/articles/10.1186/s13098-016-0142-8