

DAFTAR PUSTAKA

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LAMPIRAN

Lampiran 1. Formulir Persetujuan Setelah Penjelasan (PSP)



KEMENTERIAN PENDIDIKAN, KEBUDAYAAN, RISET DAN TEKNOLOGI
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FORMULIR PERSETUJUAN SETELAH PENJELASAN (PSP) (INFORMED CONSENT)

Selamat pagi Bapak / Ibu /Saudara(i), saya dr. A. Ahwal M.H. Rauf, bermaksud untuk melakukan penelitian dengan judul Pengaruh Intervensi *Repetitive Transcranial Magnetic Stimulation* (rTMS) Pada Perubahan Skor *Gugging Swallowing Screen* (GUSS) Disfagia Pasien Stroke Iskemik kepada bapak/ibu, dalam bentuk pengambilan data secara langsung meliputi mencatat identitas, wawancara, pemeriksaan neurologis, hasil pemeriksaan pencitraan kepala, dan pemeriksaan skor GUSS berupa evaluasi terhadap kesadaran, proses menelan, batuk/tersedak dan perubahan suara bapak/ibu yang dinilai sebanyak 2 (dua) kali yaitu pada sebelum dan sesudah tindakan terhadap Bapak/Ibu.

Tujuan penelitian ini adalah untuk mengetahui pengaruh rTMS terhadap perubahan skor disfagia pasien stroke iskemik berdasarkan skor GUSS. Hasil penelitian ini diharapkan dapat memberikan manfaat pengetahuan dan kontribusi terhadap *neuroscience*, khususnya pengaruh *Repetitive Transcranial Magnetic Stimulation* (rTMS) terhadap perbaikan fungsi menelan pada pasien stroke iskemik.

Setelah pengambilan data pertama, bapak/ibu akan mendapatkan dua kemungkinan perlakuan. Yang pertama adalah tindakan *repetitive transcranial magnetic stimulation* (stimulasi magnetik terhadap kepala yang berulang) dimana pada prosedur ini akan diletakkan alat stimulasi pada kepala bapak/ibu yang memancarkan gelombang elektromagnetik sehingga mempengaruhi kerja otak, dan yang kedua adalah sham protokol dimana bapak/ibu mendapatkan perlakuan berupa peletakkan alat stimulasi di kepala bapak tetapi dengan posisi yang berbeda sehingga stimulasi yang diberikan tidak mempengaruhi tubuh bapak/ibu. Prosedur ini dilakukan oleh dokter di Poliklinik Saraf RSUP Dr. Wahidin Sudirohusodo. Durasi setiap sesi protokol rTMS/sham adalah 15 menit/hari selama 10 hari. Obat untuk terapi stroke yang sudah bapak/ibu dapatkan berupa obat pengencer darah, dan fisioterapi rutin tetap dilanjutkan selama prosedur penelitian ini dan tidak mempengaruhi prosedur penelitian.

Kami akan mengambil data yang berasal dari ibu/bapak dan mencatat identitas (nama, umur, jenis kelamin, pendidikan, riwayat penyakit, riwayat

pengobatan). Selanjutnya akan dilakukan pengambilan data melalui pemeriksaan yang telah disebutkan di atas. Data yang diambil sebanyak 2 (dua) kali yaitu data awal dan setelah dilakukan Tindakan *repetitive transcranial magnetic stimulation* atau *sham protocol*. Penelitian ini dilakukan untuk memperoleh pengetahuan dan kontribusi terhadap neuroscience dan khususnya pengaruh repetitive transcranial magnetic stimulation terhadap perbaikan fungsi menelan pada pasien stroke iskemik, dapat dijadikan sebagai alternatif terapi non obat-obatan pada kasus disfagia pasca stroke, menjadi sumber referensi bagi peneliti lain dalam melakukan penelitian selanjutnya terkait dengan pengaruh repetitive transcranial magnetic stimulation terhadap disfagia. Tindakan ini cenderung aman tetapi dapat terjadi efek samping yang ringan seperti nyeri kepala dan pingsan atau efek samping yang jarang terjadi yakni kejang, gangguan kognitif, gangguan pendengaran. Untuk mencegah hal ini maka kami akan melakukan seleksi yang ketat. Dan apabila terjadi efek samping akan kami berikan pengobatan berupa pemberian obat-obatan bila muncul efek samping ringan seperti nyeri kepala dan perawatan di Rumah sakit bila muncul efek samping yang berat seperti kejang dan pingsan. Semua biaya sselama terjadi efek samping akan ditanggung oleh pihak peneliti hingga pengobatan tuntas. Selama penelitian Bapak/ibu tidak dikenakan biaya. Dan pada akhir tindakan penelitian pada bapak/ibu, akan diberikan kompensasi biaya transportasi berupa uang tunai sejumlah Rp 200.000,-.

Keikutsertaan Bapak/Ibu dalam penelitian ini bersifat sukarela tanpa paksaan, karena itu bila Bapak/Ibu menolak ikut atau berhenti ikut pada penelitian ini jangan takut akan kehilangan hak untuk mendapatkan pelayanan kesehatan standar rutin.

Data dikumpulkan dalam penelitian ini akan disimpan dalam data komputer tanpa nama Bapak/Ibu/saudara. Hanya peneliti yang mengetahui data-data Bapak/Ibu/saudara. Hasil penelitian ini akan dipublikasikan di forum ilmiah terbatas dan jurnal nasional tanpa menampilkan identitas Bapak/ibu/saudara.

Sehubungan dengan penelitian ini, bila timbul pertanyaan lebih lanjut diharapkan dapat menghubungi: dr. A. Ahwal, nomor telepon: 081340209205.

Identitas Peneliti

Nama : dr. A. Ahwal M.H. Rauf
Alamat : Jl. Keindahan I BTP Blok AA No. 1 BTP Makassar
No Hp : 0813402090205



KEMENTERIAN PENDIDIKAN, KEBUDAYAAN, RISET DAN TEKNOLOGI
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 KOMITE ETIK PENELITIAN UNIVERSITAS HASANUDDIN
 RSPTN UNIVERSITAS HASANUDDIN
 RSUP Dr. WAHIDIN SUDIROHUSODO MAKASSAR
 Sekretariat : Lantai 2 Gedung Laboratorium Terpadu
 JL.PERINTIS KEMERDEKAAN KAMPUS TAMALANREA KM.10 MAKASSAR 90245.



Contact Person: dr. Agussalim Bukhari.,MMed,PhD, SpGK TELP. 081241850858, 0411 5780103, Fax : 0411-581431

FORMULIR PERSETUJUAN SETELAH PENJELASAN

Saya yang bertandatangan di bawah ini :

Nama :
 Umur :
 Masa Kerja :
 Satuan :
 Alamat :

.....
 setelah mendengar/membaca dan mengerti penjelasan yang diberikan mengenai tujuan, manfaat, dan apa yang akan dilakukan pada penelitian ini, menyatakan setuju untuk ikut dalam penelitian ini secara sukarela tanpa paksaan.

Saya tahu bahwa keikutsertaan saya ini bersifat sukarela tanpa paksaan, sehingga saya bisa menolak ikut atau mengundurkan diri dari penelitian ini. Saya berhak bertanya atau meminta penjelasan pada peneliti bila masih ada hal yang belum jelas atau masih ada hal yang ingin saya ketahui tentang penelitian ini.

Saya juga mengerti bahwa semua biaya yang dikeluarkan sehubungan dengan penelitian ini, akan ditanggung oleh peneliti. Saya percaya bahwa keamanan dan kerahasiaan data penelitian akan terjamin dan saya dengan ini menyetujui semua data saya yang dihasilkan pada penelitian ini untuk disajikan dalam bentuk lisan maupun tulisan.

Dengan membubuhkan tandatangan saya di bawah ini, saya menegaskan keikutsertaan saya secara sukarela dalam studi penelitian ini.

	Nama	Tanda tangan	Tgl/Bln/Thn
Responden
/Wali			
Saksi

(Tanda Tangan Saksi diperlukan hanya jika Partisipan tidak dapat memberikan consent/persetujuan sehingga menggunakan wali yang sah secara hukum, yaitu untuk partisipan berikut:

1. Berusia di bawah 18 tahun
2. Usia lanjut
3. Gangguan mental
4. Pasien tidak sadar
5. Dan lain-lain kondisi yang tidak memungkinkan memberikan persetujuan

Penanggung Jawab Penelitian	Penanggung Jawab Medis
<p>Nama : dr. A. Ahwal M.H. Rauf</p> <p>Alamat : Jl. Keindahan I BTP Blok AA No. 1 BTP Makassar</p> <p>Telepon : 081340209205</p>	<p>Nama: Dr. dr. Jumraini Tammasse, Sp.S (K)</p> <p>Alamat : BTP Blok G No. 15-16 Jl. Tamalanrea Raya Makassar</p> <p>Telepon: 082188833368</p>

Lampiran 2. Rekomendasi Persetujuan Etik


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 Contact Person: dr. Agussalim Bukhari.,M.Med.,PhD., SpGK TELP. 081241850858, 0411 5780103, Fax : 0411-581431





REKOMENDASI PERSETUJUAN ETIK

Nomor : 566/UN4.6.4.5.31/ PP36/ 2022

Tanggal: 6 Oktober 2022

Dengan ini Menyatakan bahwa Protokol dan Dokumen yang Berhubungan Dengan Protokol berikut ini telah mendapatkan Persetujuan Etik :

No Protokol	UH22090514		No Sponsor	
Peneliti Utama	dr. A.Ahwal M.H. Rauf		Sponsor	
Judul Peneliti	PENGARUH INTERVENSI REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION PADA PERUBAHAN SKOR GUGGING SWALLOWING SCREEN (GUSS) DISFAGIA PASIEN STROKE ISKEMIK			
No Versi Protokol	2	Tanggal Versi	29 September 2022	
No Versi PSP	2	Tanggal Versi	29 September 2022	
Tempat Penelitian	RSUP Dr. Wahidin Sudirohusodo Makassar			
Jenis Review	<input type="checkbox"/> Exempted <input type="checkbox"/> Expedited <input checked="" type="checkbox"/> Fullboard Tanggal 28 September 2022	Masa Berlaku	6 Oktober 2022 sampai 6 Oktober 2023 Frekuensi review lanjutan	
Ketua KEP Universitas Hasanuddin	Nama Prof.Dr.dr. Suryani As'ad, M.Sc.,Sp.GK (K)		Tanda tangan 	
Sekretaris KEP Universitas Hasanuddin	Nama dr. Agussalim Bukhari, M.Med.,Ph.D.,Sp.GK (K)		Tanda tangan 	

Kewajiban Peneliti Utama:

- Menyerahkan Amandemen Protokol untuk persetujuan sebelum di implementasikan
- Menyerahkan Laporan SAE ke Komisi Etik dalam 24 Jam dan dilengkapi dalam 7 hari dan Laporan SUSAR dalam 72 Jam setelah Peneliti Utama menerima laporan
- Menyerahkan Laporan Kemajuan (progress report) setiap 6 bulan untuk penelitian resiko tinggi dan setiap setahun untuk penelitian resiko rendah
- Menyerahkan laporan akhir setelah Penelitian berakhir
- Melaporkan penyimpangan dari protokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan

Lampiran 3. Formulir Gugging Swallowing Screen

Patient's label	<h2 style="color: red; margin: 0;">G U S S</h2> <p style="color: red; margin: 0;">(Gugging Swallowing Screen)</p>	Date: _____ Time: _____ Investigator: _____
-----------------	---	---

1. Preliminary Investigation / Indirect Swallowing Test

		YES	NO
VIGILANCE	The patient must be alert for at least 15 minutes	1 <input type="checkbox"/>	0 <input type="checkbox"/>
COUGHING and/or THROAT CLEARING	Voluntary cough: The patient should cough or clear his/her throat twice	1 <input type="checkbox"/>	0 <input type="checkbox"/>
SWALLOWING SALIVA	Conduct oral hygiene if the mouth is very dry If the patient coughs during or after swallowing saliva please tick „No“	1 <input type="checkbox"/>	0 <input type="checkbox"/>
<ul style="list-style-type: none"> • Swallowing successful • Drooling • Voice change after swallowing 	Permanent severe saliva drooling Gurgling, wet hoarse voice since onset of stroke	0 <input type="checkbox"/> 0 <input type="checkbox"/>	1 <input type="checkbox"/> 1 <input type="checkbox"/>
SUM:		(5)	
		1 – 4 = Stop the test see GUSS-Evaluation 5 = Continue with part 2	

2. Direct Swallowing Test (Material: Water, food thickener, teaspoon, cup, syringe, bread, biscuit)

In the following order	SEMISOLID→	LIQUID→	SOLID
	½ teaspoon of thickened water (IDDSI: Level 3) If there are no symptoms apply 3-5 more teaspoons Stop the investigation if one of the 4 aspiration criteria is observed	Offer 3, 5, 10, 20 ml of water in a cup followed by 50 ml of water. (sequential swallows) Stop the investigation if one of the 4 aspiration criteria is observed	Offer a piece of bread without crust and/or a piece of biscuit (max. 1.5 x 1.5cm) Stop the investigation if one of the 4 aspiration criteria is observed
DEGLUTITION			
<ul style="list-style-type: none"> ▪ Swallowing not possible ▪ Swallowing delayed (semisolids, fluids > 2 sec. solids > 10 sec.) ▪ Swallowing successful 	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/>	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/>	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/>
COUGHING (involuntary) <i>(before, during and after swallowing - until 3 minutes later)</i>			
<ul style="list-style-type: none"> ▪ Yes ▪ No 	0 <input type="checkbox"/> 1 <input type="checkbox"/>	0 <input type="checkbox"/> 1 <input type="checkbox"/>	0 <input type="checkbox"/> 1 <input type="checkbox"/>
DROOLING			
<ul style="list-style-type: none"> ▪ Yes ▪ No 	0 <input type="checkbox"/> 1 <input type="checkbox"/>	0 <input type="checkbox"/> 1 <input type="checkbox"/>	0 <input type="checkbox"/> 1 <input type="checkbox"/>
VOICE CHANGE <i>(Listen to the voice before and after swallowing - Patient should say „Ohhh“)</i>			
<ul style="list-style-type: none"> ▪ Yes ▪ No 	0 <input type="checkbox"/> 1 <input type="checkbox"/>	0 <input type="checkbox"/> 1 <input type="checkbox"/>	0 <input type="checkbox"/> 1 <input type="checkbox"/>
SUM:		(5)	(5)
		1 – 4 = Stop the test see GUSS-Evaluation 5 = Continue „Liquid“	1 – 4 = Stop the test see GUSS-Evaluation 5 = Continue „Solid“
SUM: (Indirect Swallowing Test AND Direct Swallowing Test)		_____ (20)	

**Lampiran 4. Data Hasil Penelitian
Kelompok Intervensi**

No.	Jenis Kelamin	Umur	Onset	Lokasi Infark	Skor GUSS H-1	Skor GUSS H-10	Selisih
1	Laki-laki	59	5 hari	Kapsula Interna bilateral	12	19	7
2	Laki-laki	56	3 hari	Corona radiata dextra	14	19	5
3	Laki-laki	48	2 minggu	Ganglia basalis dextra	11	18	7
4	Laki-laki	64	1 bulan	Ganglia basalis bilateral	7	14	7
5	Laki-laki	57	3 minggu	Lobus temporooccipital kanan + Ganglia basalis kanan + Pons	8	14	6
6	Laki-laki	56	1 bulan	Pons sinistra	3	7	4
7	Laki-laki	52	1 minggu	Frontotemporoparietal sinistra	13	18	5
8	Perempuan	56	3 hari	Pons	2	5	3
9	Perempuan	60	1 minggu	Thalamus dextra	14	19	5
10	Perempuan	64	1minggu	Periventrikel cornu anterior bilateral + Pons	14	19	5

Kelompok Kontrol

No.	Jenis Kelamin	Umur	Onset	Lokasi Infark	Skor GUSS H-1	Skor GUSS H-10	Selisih
1	Perempuan	57	3 minggu	Pons + Ganglia basalis bilateral	9	12	3
2	Perempuan	62	3 hari	Capsula interna sinistra	12	14	2
3	Laki-laki	46	1 bulan	Thalamus dextra + Pons	9	13	4
4	Laki-laki	52	1 bulan	Frontotemporoparietooccipital sinistra + Thalamus Bilateral + Nucleus Caudatus Kanan	13	14	1
5	Laki-laki	64	1 bulan	Lobus frontalis bilateral + Ganglia basalis bilateral + Pons sinistra + Cerebellum dextra	12	14	2
6	Laki-laki	62	2 minggu	Corona radiata dextra	8	12	4
7	Laki-laki	57	1minggu	Corona radiata bilateral + Nucleus caudatus sinistra	8	14	6
8	Perempuan	60	1 minggu	Capsula interna sinistra + Nucleus caudatus dextra + Pons sinistra	4	7	3
9	Laki-laki	65	1 minggu	Corona radiata bilateral + Lobus occipital dextra	14	18	4
10	Perempuan	65	1 minggu	Capsula interna dextra + Paraventrikel dextra	12	14	2

Lampiran 5. Analisis Statistik

Uji Normalitas Data Kelompok Intervensi

Shapiro-Wilk test		
W	0,8540	0,7542
P value	0,0649	0,0040
Passed normality test (alpha=0.05)?	Yes	No
P value summary	ns	**

Uji Normalitas Data Kelompok Kontrol

Shapiro-Wilk test		
W	0,9189	0,8366
P value	0,3480	0,0402
Passed normality test (alpha=0.05)?	Yes	No
P value summary	ns	*

Uji Normalitas Data Delta GUSS Kelompok Intervensi dan Kontrol

Shapiro-Wilk test	Intervensi	Kontrol
W	0,8960	0,9337
P value	0,1977	0,4851
Passed normality test (alpha=0.05)?	Yes	Yes
P value summary	ns	ns

Analisis Skor GUSS Kelompok Intervensi

Descriptive statistics		A	B
		Sebelum	Setelah
		Y	Y
1	Number of values	10	10
2			
3	Minimum	2.000	5.000
4	25% Percentile	6.000	12.25
5	Median	11.50	18.00
6	75% Percentile	14.00	19.00
7	Maximum	14.00	19.00
8	Range	12.00	14.00
9			
10	Mean	9.800	15.20
11	Std. Deviation	4.566	5.245
12	Std. Error of Mean	1.444	1.659
13			
14	Sum	98.00	152.0

Wilcoxon test		
Tabular results		
1	Table Analyzed	Intervensi
2		
3	Column B	Setelah
4	vs.	vs.
5	Column A	Sebelum
6		
7	Wilcoxon matched-pairs signed rank test	
8	P value	0.0020
9	Exact or approximate P value?	Exact
10	P value summary	**
11	Significantly different (P < 0.05)?	Yes
12	One- or two-tailed P value?	Two-tailed
13	Sum of positive, negative ranks	55.00 , 0.000
14	Sum of signed ranks (W)	55.00
15	Number of pairs	10
16	Number of ties (ignored)	0
17		
18	Median of differences	
19	Median	5.000
20		
21	How effective was the pairing?	
22	rs (Spearman)	0.9366
23	P value (one tailed)	0.0002
24	P value summary	***
25	Was the pairing significantly effective?	Yes

Analisis Skor GUSS Kelompok Kontrol

Descriptive statistics		A	B
		Sebelum	Setelah
		Y	Y
1	Number of values	10	10
2			
3	Minimum	4.000	7.000
4	25% Percentile	8.000	12.00
5	Median	10.50	14.00
6	75% Percentile	12.25	14.00
7	Maximum	14.00	18.00
8	Range	10.00	11.00
9			
10	Mean	10.10	13.20
11	Std. Deviation	3.035	2.741
12	Std. Error of Mean	0.9597	0.8667
13			
14	Sum	101.0	132.0

Table Analyzed	Kontrol
Column B	Setelah
vs.	vs.
Column A	Sebelum
Wilcoxon matched-pairs signed rank test	
P value	0.0020
Exact or approximate P value?	Exact
P value summary	**
Significantly different (P < 0.05)?	Yes
One- or two-tailed P value?	Two-tailed
Sum of positive, negative ranks	55.00 , 0.000
Sum of signed ranks (W)	55.00
Number of pairs	10
Number of ties (ignored)	0
Median of differences	
Median	3.000
How effective was the pairing?	
rs (Spearman)	0.8129
P value (one tailed)	0.0032
P value summary	**
Was the pairing significantly effective?	Yes

Analisis Delta GUSS

Descriptive statistics		A	B
		Intervensi	Kontrol
		Y	Y
1	Number of values	10	10
2			
3	Minimum	3.000	1.000
4	25% Percentile	4.750	2.000
5	Median	5.000	3.000
6	75% Percentile	7.000	4.000
7	Maximum	7.000	6.000
8	Range	4.000	5.000
9			
10	Mean	5.400	3.100
11	Std. Deviation	1.350	1.449
12	Std. Error of Mean	0.4269	0.4583
13			
14	Sum	54.00	31.00

Table Analyzed	Delta
Column B	Kontrol
vs.	vs.
Column A	Intervensi
Unpaired t test	
P value	0.0017
P value summary	**
Significantly different (P < 0.05)?	Yes
One- or two-tailed P value?	Two-tailed
t, df	t=3.672, df=18
How big is the difference?	
Mean of column A	5.400
Mean of column B	3.100
Difference between means (B - A) ± SEM	-2.300 ± 0.6263
95% confidence interval	-3.616 to -0.9842
R squared (eta squared)	0.4283
F test to compare variances	
F, DFn, Dfd	1.152, 9, 9
P value	0.8361
P value summary	ns
Significantly different (P < 0.05)?	No
Data analyzed	
Sample size, column A	10
Sample size, column B	10

Analisis Kemampuan Menelan

Kemampuan_Menelan * Intervensi Crosstabulation

		Intervensi		Total	
		Pre	Post		
Kemampuan_Menelan	Semisolid_Likuid	Count	0	6	6
		Expected Count	3.0	3.0	6.0
	Semisolid	Count	6	2	8
		Expected Count	4.0	4.0	8.0
	Indirek	Count	2	2	4
		Expected Count	2.0	2.0	4.0
	No_indirek	Count	2	0	2
		Expected Count	1.0	1.0	2.0
	Total	Count	10	10	20
		Expected Count	10.0	10.0	20.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)
Pearson Chi-Square	10.000 ^a	3	.019	.0088
Likelihood Ratio	13.183	3	.004	.0088
Fisher-Freeman-Halton Exact Test	9.696			.0088
N of Valid Cases	20			

a. 8 cells (100.0%) have expected count less than 5. The minimum expected count is 1.00.

Kemampuan_Menelan * Kontrol Crosstabulation

		Kontrol		Total	
		Pre	Post		
Kemampuan_Menelan	Semisolid_Likuid	Count	0	1	1
		Expected Count	.5	.5	1.0
	Semisolid	Count	5	8	13
		Expected Count	6.5	6.5	13.0
	Indirek	Count	4	1	5
		Expected Count	2.5	2.5	5.0
	No_indirek	Count	1	0	1
		Expected Count	.5	.5	1.0
	Total	Count	10	10	20
		Expected Count	10.0	10.0	20.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)
Pearson Chi-Square	4.492 ^a	3	.213	.2105
Likelihood Ratio	5.399	3	.145	.2105
Fisher-Freeman-Halton Exact Test	4.181			.2105
N of Valid Cases	20			

a. 6 cells (75.0%) have expected count less than 5. The minimum expected count is .50.