The Effectiveness of the Video Conferencing Telerehabilitation Method, Delivered in One on One and Group Sessions, in Urinary Incontinence Cases.

Study Protocol and Statistical Analysis Plan (SAP) (Pages 1 – 21)

November 15,2021

The Effectiveness of the Video Conferencing Telerehabilitation Method, Delivered in One on One and Group Sessions, in Urinary Incontinence Cases.

Study Protocol (Pages 2-6)

November 15,2021

Study Protocol

Study titled "The Effectiveness of the Video Conferencing Telerehabilitation Method, Delivered in One on One and Group Sessions, in Urinary Incontinence Cases." was approved by Marmara University Faculty of Medicine Ethical Committee at the meeting on 30.11.2020 with approval number: 1195 (Annex-1).

The legal representatives of the patients who participated in the study will be informed about the aim, duration and the programs to be applied throughout the study. Volunteer Information Form will be signed and approved in accordance with the standards deemed appropriate by the Ethical Committee of Marmara University Faculty of Medicine. The study will be conducted in accordance with the Declaration of Helsinki.

Hypothesis of the Study

H0: With one on one video conference method, exercise training is no superiority of exercise training with group video conferencing method in urinary incontinence.

H1: Exercise training with one on one video conference method is more effective in increasing muscle strength in patients with urinary incontinence.

H2: One on one videoconferencing and exercise training are more effective in reducing the degree of incontinence in patients with urinary incontinence.

H3: Exercise training with one on one videoconferencing method is more effective in increasing the quality of life in patients with urinary incontinence.

H4: Exercise training with one on one videoconferencing method is more effective in increasing patient satisfaction in patients with urinary incontinence.

H5: Exercise training with one on one video conference method is more effective in increasing sexual function in patients with urinary incontinence.

H6: Exercise training with one on one videoconferencing method is more effective in increasing exercise adherence in patients with urinary incontinence.

Randomization of the Study Groups

Individuals with Urinary Incontinence applying to Göztepe Prof. Dr. Süleyman Yalçın Şehir Hastanesi will be invited to participate in the study. Individuals who volunteered to participate and whom met the criteria for participation will be randomized with simple random sampling method and will be

divided into two groups. In both groups participants will receive same exercise program and physiotherapist will follow up the exercise program every week by video confernce method. While only the physiotherapist and the patient will take part in the one-on-one group, there will be a physiotherapist and 8 patients in the group sessions.

Inclusion Criteria

18-65 aged

BMI 18-30 kg/m2

Being diagnosed with stress incontinence or mixed incontinence (dominantly SUI) Mild or moderate incontinence (mild SUI; urinary incontinence with coughing, sneezing, laughing, or any strenuous activity. Moderate; urinary incontinence with carrying, pushing, lifting, walking, and any light physical activity)

Exclusion Criteria

Pregnancy Ongoing vulvovaginitis or urinary tract infection or malignancy Pelvic floor muscle strength is between 0-1 according to the Modified Oxford Scale, Previous surgery for SUI Problems with vision or inability to understand given commands Conservative therapy in the last 6 months Allergic reaction to the gel used with the perinometer/probe

Evaluations

Evaluation parameters will be applied at the baseline, at the end of 4-weeks treatment program, at the end of 8 weeks treatment program. Outcome measures and applied evaluations are shown in Table 1.

 Table 1. Outcome measures and evaluation methods

Primary Outcome Measures	Evaluation Methods
Mussla Strangth	-PERFECT Scheme
Muscle Strength	-Surface Electromyography

Secondary Outcome Measures	Evaluation Methods
	-1 hour pad test
	-The International Consultation on Incontinence Questionnaire- Short Form
Symptom Evaluation	- Urogenital Distress Inventory- 6 (UDI-6)
	- Incontinence Impact Questionnaire-7 (IIQ-7)
	- Overactive Bladder -Validated 8- Question Awereness Tool (OAB-V8)
Patient Satisfaction	Visual Analog Scale (VAS)
Exercise Adherence	VAS Broome Pelvic Floor Muscle Exercise Self- Efficiacy Scale
Sexual Function	Female Sexual Function Scale (FSFI)

Treatment Program

The exercises which given the both groups compose same exercise protocols for 8 week. The exercise protocol includes pelvic floor muscle training, diaphragmatic breathing exercise and core exercise will be given the all participants. The participants in the study will be followed up with video conferecing method by weekly.

Group I (one on one video conferencing group): In this group, exercise follow-up and transition to the next exercise phase will be realized with one-on-one video conference interviews.

Group II (group sessions video conferencing group): In this group, exercise follow-up and transition to the next exercise stage will be realized with group video conference sessions consisting of 8 participants.

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Statistical Analysis Plan (SAP) (Pages 7-8)

November 15,2021

Statatistical Analysis Plan (SAP)

In the analysis of the data to be obtained in the study, the significance will be evaluated at the p<0.05 level with the SPSS 22.0 statistical program at the 90% confidence interval. In the evaluation of variables; If the number of cases is sufficient, its conformity to the normal distribution will be questioned with the Kolmogorov Smirnov test and normal distribution graphs. In the examination of the variables, appropriate statistical tests will be applied depending on the provision of parametric or non-parametric test conditions. Normally distributed variables will be expressed as mean and standard deviation, and non-normally distributed variables will be expressed as numbers and percentages. If the groups fit the normal distribution, the evaluation results at the beginning, 4th week and 8th week will be compared with ANOVA, if the normal distribution is not met, comparisons will be made with Kruskal Wallis and appropriate post-hoc tests. In the correlation analysis, the appropriate Speerman or Pearson correlation analysis methods will be preferred. Chi-square test will be used in the evaluation of binary data.

The Effectiveness of the Video Conferencing Telerehabilitation Method, Delivered in One on One and Group Sessions, in Urinary Incontinence Cases.

Annex (Pages 9 – 21)

November 15,2021

Annex 1. Marmara University Faculty of Medicine Ethical Committee Approval (Approval made at the meeting on 30.11.2020 with number: 1195)

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		Marmara Ün Klinik Araştı	iversites rmalar I	Tip Fi Etik Ku	akültesi ırulu			
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Prof.Dr. Atila KARAALP	Farmakoloji	M.Ü Tıp Faküli	esi/Oye	Var	0 Yok	Ever	HAYER	1
Prof. Dr. Şefik GÖRKEY	Tıp Tarihi ve Etik	MLÜ Tıp Fakülı	esi/Oye	Var	Yok	Evet	Hayır	1 from
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Prof.Dr. M.Bahadır GÜLLÜOĞL	U Genel Cerrahi	M.Ö Tıp Fakült	esi/Öye	Var	Yok	Evet	Hayır	MEZ
Prof.Dr. Semra SARDAŞ	Eczaci	M.Č Eczacilik F	ak/Cye	Var	Yok	0 Evet	0 Hayır	
Pref.Dr. Bajak DOĞAN	Diş Hekimi	M.Ü Diş Hekimliği	i Fak./Öye	Var	Yok	Evet	Hayır	195
Prof. Dr. Bestr Melek ATASOY	Radyasyon Onkolojisi	M.O Tip Fakili	esi/Öye	Var	Yok	Evet	Hayır	X
Prof. Dr., Elf KARAKOÇ AYDINER	Çocuk Sağlığı ve Hastalıkları	M.O Tip Fakült	esi/Oye	Var	Yok	Evet	Hayır	and a
Prof.,Dr. Melten KORAY	Diş Hekimi	İstanbul Oniv. Diş Fak/Öye		Var	Yok	Evet	Hayır	
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Annex 2. Patient Evaluation Form

DATE:

PATIENT EVALUATION FORM

NAME-SURNAME: SEX: **BİRTH DATE/AGE:** WEIGHT: **HEIGHT:** BMI: EDUCATION LEVEL: MARITUAL STATUS: **PHONE NUMBER:** TYPE OF BİRTH: NUMBER OF BİRTH: **MENOPEASE STATUS:** WEEKLY ALCOHOL CONSUMPTION:/ week WEEKLY TEA CONSUMPTION:/week MEDİCAL HİSTORY:

DRUGS USED:

Annex 3. Assessment of Muscle Strength

	PERFECT SCHEME					
	Power	Endurance	Repetitions	Fast Contraction	Every Contraction Time	
	(P)	(E)	(R)	(F)	(ECT)	
1						
2						
3						
MEAN						

	Surface EMG							
		Maximum						
	Resting	Voluntary	Pelvic Floor					
	tone	Contraction	Muscle Endurance					
		(MVC)						
1								
2								
3								
Mean								

Annex 4. International Consultation on Incontinence Questionnaire-Urinary Incontinence Short

Form

	ICIQ-UI Short F	orm		
Initial number	CONFIDEN	ΓIAL	DAY	MONTH YEAR
Many people leak urine som and how much this bothers questions, thinking about ho	s them. We would be	grateful if yo	ut how many ou could an	people leak urine, swer the following
1 Please write in your dat	e of birth:			NTH YEAR
2 Are you (tick one):		_	male	
3 How often do you leak u	irine? (Tick one box)			
		about anos	a wook or loo	never 0
		about once a	three times	
			about onc	
			several time	
				he time 5
			a small a a moderate a a large a	amount 4
5 Overall, how much does Please ring a number bet	-	-		? ?
0 1 not at all	2 3 4 5 6	678	9 10 a great	deal
		ICIQ score: su	um scores 3+	+4+5
6 When does urine leak?	(Please tick all that app			
	laa		urine does r	
		ks before you leaks when yo	•	
		-	hen you are	
	leaks when yo		-	
	leaks when you have f		÷	
		leaks for	r no obvious	
			leaks all t	

Thank you very much for answering these questions.

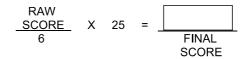
Copyright © "ICIQ Group"

Annex 5. Urogenital Distress Inventory (Udi 6)

UROGENITAL DISTRESS INVENTORY (UDI 6)

Do you experience? If so how much are you bothered by:

	Not at all	A little bit	Moderately	Greatly
1. Frequent urination?	0	1	2	3
2. Urine leakage related to the feeling of urgency?	0	1	2	3
3. Urine leakage related to physical activity, coughing or sneezing?	0	1	2	3
4. Small amounts of urine leakage (that is drops)?	0	1	2	3
5. Difficulty emptying your bladder?	0	1	2	3
6. Pain or discomfort in the lower abdominal or genital area?	0	1	2	3



Annex 6. Incontinence Impact Questionnaire, Short Form (I1q-7)

OREGON	Patient Name:
HEALTH	Date of Birth:
& SCIENCE	MRN:
UNIVERSITY	Date of Service:
Urology	Physician:

Incontinence Impact Questionnaire, Short Form (IIQ-7)

Some people find that accidental urine loss may affect their activities, relationships, and feelings. For each question, circle the response that best describes how much your activities, relationships, and feelings are being affected by urine leakage over the past month.

	Not at All	Slightly	Moderately	Greatly
Ability to do household chores (cooking, housecleaning, laundry)?	0	1	2	3
Physical recreation such as walking, swimming, or other exercise?	0	1	2	3
Entertaining activities (movies, concerts, etc.)?	0	1	2	3
Ability to travel by car or bus more than 30 minutes from home?	0	1	2	3
Participation in social activities outside your home?	0	1	2	3
Emotional health (nervousness, depression, etc.)?	0	1	2	3
Feeling frustrated?	0	1	2	3

Has urine leakage (incontinence) affected your:

Adapted from Uebersax JS, Wyman FF, Shumaker SA, et al. Short forms to assess life quality and symptom distress for urinary incontinence in women: the incontinence impact questionnaire and urogenital distress inventory. Neurourol Urodyn 1995; 14: 131.

Annex 7. Assessment of Patient Satisfaction

1) How satisfied were you w	with the treatment you receive	ed?
0	5	10
(Not satisfied at all)		(Very satisfied)
2) How satisfied were you w	vith the decrease in your com	plaints after your treatment?
0	5	10
(Not satisfied at all)		(Very satisfied)
3) How satisfied were you th	nat your exercise program is	followed by online interviews?
0	5	10
(Not satisfied at all)		(Very satisfied)

Annex 8. Assesment of Exercise Adherence

- Visual Analog Scale

How long did you adhere to the exercise program during your treatment?

0	5	10
(Not satisfied at all)		(Very satisfied)

- Broome Pelvic Muscle Exercise Self Efficiacy Scale

Question	Level of Confidence
Part A: How confident are you that you can:	
1. Contract your pelvic muscles?	0 10 20 30 40 50 60 70 80 90 100
2. Perform pelvic muscle contractions three times a day?	0 10 20 30 40 50 60 70 80 90 100
3. Perform pelvic muscle contractions while lying down?	0 10 20 30 40 50 60 70 80 90 100
4. Perform pelvic muscle contractions while standing?	0 10 20 30 40 50 60 70 80 90 100
5. Perform pelvic muscle contractions while sitting?	0 10 20 30 40 50 60 70 80 90 100
6. Contract your pelvic muscles without contracting your abdominal muscles?	0 10 20 30 40 50 60 70 80 90 100
7. Contract your pelvic muscles while washing fruits under running water?	0 10 20 30 40 50 60 70 80 90 100
8. Contract your pelvic muscles when lifting a bag of groceries?	0 10 20 30 40 50 60 70 80 90 100
9. Contract your pelvic muscles while standing at the sink brushing your teeth?	0 10 20 30 40 50 60 70 80 90 100
10. Contract your pelvic muscles rapidly?	0 10 20 30 40 50 60 70 80 90 100
11. Perform pelvic muscle contractions when you are sad?	0 10 20 30 40 50 60 70 80 90 100
12. Contract your pelvic muscles while showering after a busy and tiring day?	0 10 20 30 40 50 60 70 80 90 100
13. Perform pelvic muscle contractions when you are tired?	0 10 20 30 40 50 60 70 80 90 100
14. Contract your pelvic muscles when you awaken at night with a strong urge to urinate?	0 10 20 30 40 50 60 70 80 90 100
Part B: How confident are you that pelvic muscle contractions will prevent unwanted urine loss:	
1. When you experience a strong urge to urinate?	0 10 20 30 40 50 60 70 80 90 100
2. When you sneeze?	0 10 20 30 40 50 60 70 80 90 100
3. When you laugh?	0 10 20 30 40 50 60 70 80 90 100
4. While waiting 2 minutes for a restroom?	0 10 20 30 40 50 60 70 80 90 100
5. While waiting 5 minutes for a restroom?	0 10 20 30 40 50 60 70 80 90 100
6. When you wake up at night with a strong urge to urinate?	0 10 20 30 40 50 60 70 80 90 100
7. When you lift a heavy package?	0 10 20 30 40 50 60 70 80 90 100
8. When you cough?	0 10 20 30 40 50 60 70 80 90 100
9. When washing fruits and vegetables?	0 10 20 30 40 50 60 70 80 90 100

^a Reprinted, with permission of the publisher, the Society of Urologic Nurses and Associates Inc, from: Broome B. Psychometric analysis of the Broome Pelvic Muscle Self-Efficacy Scale in African-American women with incontinence. Urol Nurs. 2001;21:289–297.

Annex 9. Female Sexual Function Index Score

Question

Q1: Over the past 4 weeks, how often did you feel sexual desire or interest?

Q2: Over the past 4 weeks, how would you rate your **level** (degree) of sexual desire or interest?

Q3. Over the past 4 weeks, how often did you feel sexually aroused ("turned on") during sexual activity or intercourse?

Q4. Over the past 4 weeks, how would you rate your **level** of sexual arousal ("turn on") during sexual activity or intercourse?

Q5. Over the past 4 weeks, how **confident** were you about becoming sexually aroused during sexual activity or intercourse?

Q6. Over the past 4 weeks, how **often** have you been satisfied with your arousal (excitement) during sexual activity or intercourse? Response Options Response Options

- 5 = Almost always or always
- 4 = Most times (more than half the time)
- 3 = Sometimes (about half the time)
- 2 = A few times (less than half the time)
- 1 = Almost never or never
- 5 = Very high
- 4 = High
- 3 = Moderate
- 2 = Low
- 1 = Very low or none at all
- 0 = No sexual activity
- 5 = Almost always or always
- 4 = Most times (more than half the time)
- 3 = Sometimes (about half the time)
- 2 = A few times (less than half the time)
- 1 = Almost never or never
- 0 = No sexual activity
- 5 = Very high
- 4 = High
- 3 = Moderate
- 2 = Low
- 1 = Very low or none at all
- 0 = No sexual activity
- 5 = Very high confidence
- 4 = High confidence
- 3 = Moderate confidence
- 2 = Low confidence
- 1 = Very low or no confidence
- 0 = No sexual activity
- 5 = Almost always or always
- 4 = Most times (more than half the time)
- 3 = Sometimes (about half the time)
- 2 = A few times (less than half the time)
- 1 = Almost never or never

Q7: Over the past 4 weeks, how often did you become lubricated ("wet") during sexual activity or intercourse?

Q8. Over the past 4 weeks, how difficult was it to become lubricated ("wet") during sexual activity or intercourse?

Q9: Over the past 4 weeks, how often did you maintain your lubrication ("wetness") until completion of sexual activity or intercourse?

Q10: Over the past 4 weeks, how difficult was it to maintain your lubrication ("wetness") until completion of sexual activity or intercourse?

Q11. Over the past 4 weeks, when you had sexual stimulation or intercourse, how often did you reach orgasm (climax)?

Q12: Over the past 4 weeks, when you had sexual stimulation or intercourse, how difficult was it for you to reach orgasm (climax)?

Q13: Over the past 4 weeks, how satisfied were you with your ability to reach orgasm (climax) during sexual activity or intercourse?

Q14: Over the past 4 weeks, how satisfied have you been with the amount of emotional closeness during sexual activity between you and your partner?

- 0 = No sexual activity
- 5 = Almost always or always
- 4 = Most times (more than half the time)
- 3 = Sometimes (about half the time)
- 2 = A few times (less than half the time)
- 1 = Almost never or never

0 = No sexual activity

- 1 = Extremely difficult or impossible
- 2 = Very difficult
- 3 = Difficult
- 4 = Slightly difficult 5 = Not difficult
- 0 = No sexual activity
- 5 = Almost always or always
- 4 = Most times (more than half the time)
- 3 = Sometimes (about half the time)
- 2 = A few times (less than half the time)
- 1 = Almost never or never
- 0 = No sexual activity
- 1 = Extremely difficult or impossible
- 2 = Very difficult
- 3 = Difficult
- 4 = Slightly difficult
- 5 = Not difficult
- 0 = No sexual activity
- 5 = Almost always or always
- 4 = Most times (more than half the time)
- 3 = Sometimes (about half the time)
- 2 = A few times (less than half the time)
- 1 = Almost never or never
- 0 = No sexual activity
- 1 = Extremely difficult or impossible
- 2 = Very difficult
- 3 = Difficult.
- 4 = Slightly difficult
- 5 = Not difficult
- 0 = No sexual activity
- 5 = Very satisfied 4
- 4 = Moderately satisfied
- 3 = About equally satisfied and dissatisfied
- 2 = Moderately dissatisfied
- 1 = Very dissatisfied
- 0 = No sexual activity
- 5 = Very satisfied
- 4 = Moderately satisfied
- 3 = About equally satisfied and dissatisfied 2 = Moderately dissatisfied
- 1 = Very dissatisfied

Q15: Over the past 4 weeks, how satisfied have you been with your sexual relationship with your partner?	 5 = Very satisfied 4 = Moderately satisfied 3 = About equally satisfied and dissatisfied 2 = Moderately dissatisfied 1 = Very dissatisfied
Q16: Over the past 4 weeks, how satisfied have you been with your overall sexual life?	 5 = Very satisfied 4 = Moderately satisfied 3 = About equally satisfied and dissatisfied 2 = Moderately dissatisfied 1 = Very dissatisfied
Q17: Over the past 4 weeks, how often did you experience discomfort or pain during vaginal penetration?	0 = Did not attempt intercourse I = Almost always or always 2 = Most times (more than half the time) 3 = Sometimes (about half the time) 4 = A few times (less than half the time) 5 = Almost never or never
Q18: Over the past 4 weeks, how often did you experience discomfort or pain follow- ing vaginal penetration?	0 = Did not attempt intercourse 1 = Almost always or always 2 = Most times (more than half the time) 3 = Sometimes (about half the time) 4 = A few times (less than half the time) 5 = Almost never or never
Q19. Over the past 4 weeks, how would you rate your level (degree) of discomfort or pain during or following vaginal penetration?	0 = Did not attempt intercourse 1 = Very high 2 = High 3 = Moderate 4 = Lene

- 4 = Low 5 = Very low or none at all

* For the complete FSFI questionnaire, instructions and scoring algorithm, please see www.FSFkquestionnaire.com, or contact Raymond Rosen Ph.D., (Department of Psychiatry: UMDNJ-Robert Wood Johnson Medical School, 675 Hoes Lane, Piscataway, NJ 08854)

OAB-V8 Overactive Bladder-**Validated** 8-question Screener¹

The questions below ask about how bothered you may be by some bladder symptoms. Some people are bothered by bladder symptoms and may not realize that there are treatments available for their symptoms. Please circle the number that best describes how much you have been bothered by each symptom. Add the numbers together for a total score and record the score in the box provided at the bottom.

How bothered have you been by	Not at all	A little bit	Some- what	Quite a bit	A great deal	A very great deal		
1. Frequent urination during the daytime hours?	0	1	2	3	4	5		
2. An uncomfortable urge to urinate?	0	1	2	3	4	5		
3. A sudden urge to urinate with little or no warning?	0	1	2	3	4	5		
4. Accidental loss of small amounts of urine?	0	1	2	3	4	5		
5. Nighttime urination?	0	1	2	3	4	5		
6. Waking up at night because you had to urinate?	0	1	2	3	4	5		
7. An uncontrollable urge to urinate?	0	1	2	3	4	5		
8. Urine loss associated with a strong desire to urinate?	0	1	2	3	4	5		
Are you male?	If m	If male 🔲 add 2 points to your score						

Please add up your responses to the questions above

Please hand this page to your doctor when you see him/her for your visit.

If your score is 8 or greater, you may have overactive bladder. There are effective treatments for this condition. You may want to talk with a healthcare professional about your symptoms.

Note: You may be asked to give a urine sample. Please ask before going to the bathroom. Reference: 1. Data on file. Pfizer Inc, New York, NY.