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TITLE: Collaborative Research and Support of Fitzsimmons Army Medical Center DWH Research Program Projects

SUBTITLE: Evaluation of the Performance Impact and Treatment of Exercise Induced Urinary Incontinence Among Female Soldiers

Protocol 6

PRINCIPAL INVESTIGATOR: Robert L. Hayes
Scott Bennion, COL
Gary Davis, COL
Richard Sherman, LTC

CONTRACTING ORGANIZATION:

Facilitators of Applied Clinical Trials
San Antonio, TX 78216

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6. AUTHOR(S)
Robert L. Hayes & Scott Bennion, COL
COL Gary Davis, M.D.
LTC Richard Sherman, Ph.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Facilitators of Applied Clinical Trials
San Antonio, Texas 78216

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No large studies have determined the incidence of urinary incontinence among female soldiers or its impact on their ability to perform their duties. Likewise, no studies have been performed to determine the effectiveness of currently accepted treatments such as surgery for stress incontinence and propantheline for urge incontinence or of experimental treatments such as urinary tract biofeedback for these problems. We are evaluating these issues by (a) having one thousand female soldiers assigned to participating combat and combat support units to fill out an anonymous questionnaire about exercise related urinary incontinence, (b) having 300 of these soldiers receive a urodynamic assessment and a volume loss test, and (c) having 100 of them receive either pelvic floor strengthening exercises or exercises plus EMG biofeedback.

The subjects examined thus far have indicated that urinary incontinence imposes a major negative impact on the soldier's ability to perform required exercises and duties. Urinary incontinence is a significant determent to job satisfaction and morale. So far biofeedback / Keegal exercises are effective in alleviating urge and mixed urinary incontinence in over one-half of the symptomatic soldiers. Urinary stress incontinence is frequently worse and precipitating injuries to the pelvic floor appear more common during the luteal phase of the menstrual cycle.

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16 August, 1995

Principal Investigator

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1. INTRODUCTION:

a. **Objectives**:

(1) To determine the incidence of exercise induced urinary incontinence among female soldiers

(2) To determine the impact of urinary incontinence upon female soldiers' ability to perform their exercises and tasks.

(3) To determine the effectiveness of standard treatments for exercise induced stress and urge urinary incontinence.

(4) To determine the effectiveness of urinary tract biofeedback and exercise training for stress and urge urinary incontinence.

b. **Hypotheses**:

(1) That about one third of female soldiers will have at least moderate exercise induced urinary incontinence with at least ten percent having the problem to such an extent that they have to drop out of training programs such as airborne.

(2) That exercise related urinary incontinence produces a significant impact upon female soldiers' ability to perform their exercises and tasks.

(3) That standard surgical interventions for exercise induced stress incontinence are generally effective but that medicinal treatments for urge incontinence produce side effects too severe for the treatment to be used with female soldiers who will participate in field exercises or other work involving the need to sweat.

(4) That urinary tract biofeedback combined with exercise training for stress and urge urinary incontinence will be sufficiently effective for about half of the female soldiers that they can take the PT test without dehydrating themselves and that a large minority will not require further treatment.

c. **Status**:

(1) Detailed summary:

Pilot work performed by the principal investigator indicates that about one third of female soldiers have problems with urinary incontinence during exercises and field training. For example, about 12% of female soldiers had to drop out of airborne training due to urinary incontinence which developed during training. No large studies have been done to determine the impact problems with urinary incontinence has upon female soldiers' abilities to perform their tasks and participate in field exercises. Likewise, no studies have be performed to determine the effectiveness of currently accepted treatments such as surgery for stress incontinence and propantheline for urge incontinence or of experimental treatments such as urinary tract biofeedback for these problems.

We propose to evaluate the extent of this problem and its impact on the ability of female solders to perform their tasks by asking one thousand female soldiers assigned to participating combat and combat support units to fill out an anonymous questionnaire about (1) any problems with exercise related urinary incontinence and (2) its impact on their ability to perform their duties in both garrison and field environments. The questionnaire contains a cover sheet which explains (1) that filling out the form is voluntary, (2) that it is anonymous, (3) that pilot data show that exercise induced urinary incontinence seems to be very common among female soldiers so we are trying to find out more about it, and (4) that effective treatments for most types are available so

they do not have to suffer in silence or drop out of Army courses due to the problem. The questionnaire also contains a detachable card with contact phone numbers so soldiers with sufficient problems who would like treatment can keep the card and call to arrange treatment. The requirement for one thousand participants is based on the need to differentiate the effects of type of incontinence, severity of incontinence, MOS, and parity assuming that about one third of women have at least moderate problems with urinary incontinence during the PT test and that there should be a 95% chance that the results will be within five percent of the actual rate of occurrence in these subgroups.

It is anticipated that 300 of the soldiers completing the interview will report significant urinary incontinence. Each of them will be offered the opportunity to have their problem evaluated. The evaluation will consist of a urine volume loss test and a urodynamic test. The urine volume loss test is performed during a simulated or real PT test and consists of (a) drinking 500 ml. of electrolyte balanced fluid within one hour of the test, (b) wearing a pre-weighed absorbent pad during the test, and (c) placing the pad into a plastic bag after the test so it can be weighed to determine how much urine was lost during the test. Sweat absorbed into the pad is of relatively inconsequential weight and should remain relatively consisted between tests.

Each subject will undergo a standard evaluation of the lower urinary tract, which will include a detailed urogynecologic history, genitourinary physical, and neurologic examination, and a urodynamic evaluation. The urodynamic evaluation will include uroflometry with post void residual urine volume measurement, retrograde provocative water cystometry, resting and stressed urethral axis determination, and direct visualization testing for fluid loss with stress. Each subject will have a negative urine culture before being scheduled for urodynamic testing.

The condition of genuine stress incontinence will be diagnosed if the subject has the symptom of stress incontinence, observable leakage produced by stress, and yet demonstrates no detrusor activity during cystometry.

A subject will be classified as having urge incontinence if she complains of involuntary loss of urine while experiencing a strong desire to urinate.

The diagnosis of motor/urge incontinence will be made when a subject demonstrates urinary incontinence due to detrusor instability during urodynamic testing.

Any subject with urge incontinence who demonstrates detrusor contractions and urinary leakage during the cystometrogram, while she is attempting to inhibit micturition, will be classified as having detrusor instability.

When a subject complains of both stress and urge incontinence, she will be classified as having the symptom of mixed incontinence.

The diagnosis of mixed incontinence will be given to those subjects who demonstrate the diagnostic criteria for both genuine stress and motor incontinence.

These criteria are consistent with the recommendations of the International Continence Society.

We also propose to test the effectiveness of current and experimental intervention programs by working with 100 female soldiers in combat or combat support units who contact OB-GYN at Madigan AMC or Fitzsimons AMC about exercise induced urinary incontinence. Almost all will be drawn from the above cohort of screened patients. Any who are not from this group will receive the same screening. They will be given an explanation of the treatment portion of this study regardless of whether they responded to the card associated with the questionnaire or contacted OB-GYN directly. All women will be offered the best treatment available for their problem regardless of whether they participate in the study. Soldiers will be sorted by diagnosis into stress, mixed, and motor/urge incontinence groups and treated as follows:

(1) Stress incontinence: The accepted treatment is surgery. Patients who do not want surgery will drop out of the study and receive the best non-surgical treatments available. While patients are waiting for their surgery dates, they will be sequentially assorted into groups receiving either (a) urinary tract biofeedback and Keegal exercises or (b) only Keegal exercises while on the

waiting list. No placebo group will be run as a comparable, realistic one has not been developed for this situation.

Subjects in the **biofeedback** group will receive half hour treatments three times per week and practice related exercises at home twice per day for ten minutes each session. Biofeedback treatments for urinary incontinence usually take about four weeks which is well within the waiting period for surgery.

(2) Motor/urge and mixed incontinence: The accepted treatment is drug therapy primarily with propantheline bromide (Pro-Banthine). This has significant side effects for active people because it interferes with sweating so treatment is normally delayed until all other possibilities are explored. During a two week waiting and decision period prior to beginning medication, soldiers will be sorted and treated as in "1" above with either (a) urinary tract biofeedback and Keegal exercises or (b) only Keegal exercises prior to beginning medicines.

For patients who receive biofeedback, (1) After initial biofeedback treatment, each will be given the (a) volume loss test and (b) the urological evaluation, and (2) those who do not desire surgical or medicinal intervention will continue in the study and will be told that, if they change their minds, they can go to the head of the waiting list for surgical intervention or for an appointment for medicinal intervention for the next year.

After the biofeedback / waiting period, all patients desiring it will receive the standard treatment after the waiting period and, after surgical recovery or stabilization on medication, each will receive the (a) volume loss test and (b) the urological evaluation.

All subjects will receive the (a) volume loss test and (b) the urological evaluation six months after the end of their treatment.

(2) **Occurrence**: Pelvic relaxation associated with urethrocele and/or cystocele has usually been ascribed to a generalize relaxation or attenuation and strengthening of the connective tissue of the anterior quadrant of the pelvic. The etiology of pelvic relaxation has been traditionally assigned to injuries sustained at childbirth, and indeed pelvic relaxation and the resultant urinary stress incontinence are correlated with both parity and age. However, this concept does not explain the incidence of urinary incontinence in nulliparous females, variously reported as occurring from 5 to 25 percent of those interviewed. The concept that pelvic relaxation, and urinary incontinence could result from an isolated defect was first explored by Richardson in 1976.

Nicholes noted "In North America approximately 2% of women who develop prolapse are nullipara. Often nulliparous prolapse will be associated with a lifestyle of heavy physical labor producing marked increases in intra-abdominal pressure. Although the etiology is doubtless complex, and due to the interaction of multiple factors, this study explores the relationship of physical training, exercise, and other factors including parity with incontinence.

Taimela studied the risk factors associated with athletic injuries and classified injuries into to categories:
(I) Traumatic in which an accident or external force is involved in the injury mechanism.
(II) Stress (over use) in which the injury results form repeated mechanical overload in the affected tissues when the ability of the tissue to regenerate is exceeded.

It is plausible that, in these patients, continued rigorous exercise combined with abrupt increases in intra-abdominal pressure led to mechanical overload, and exceeded the tissues' ability to regenerate.
McGuire reported that 27% of the subjects in his study with stress incontinence also had detrusor instability demonstrated urodynamically pre-operatively. The majority of these subjects demonstrated no detrusor instability after surgical correction. However, no studies have been performed relating the effect of biofeedback to detrusor instability.

(3) Biofeedback for exercise induced urinary incontinence: Biofeedback is simply the a

process in which the patient is shown exactly how a physiologic parameter is functioning from moment to moment. The information is used to correct abnormalities in the parameter's functioning. For example, jaw aches due to sustained, elevated masseter muscle tension can be reliably eliminated by showing patients the tension in their jaw muscles and teaching them to relax the muscles when they do not need to be tense. The methodology and effectiveness of biofeedback interventions have been reviewed extensively elsewhere (e.g. Amar et al 1992, Sherman and Arena 1992).

Numerous small, controlled studies have shown that urinary tract biofeedback can be used to teach women to significantly decrease their stress and urge incontinence related urine loss (e.g. Burton et al 1990, Taylor and Henderson 1986, Burns et al 1990 and 1993, McIntosh et al 1993). About sixty percent of women participating in these studies became more continent and about half of those were cured of the problem. Follow-ups are up to a year. Unfortunately studies including physically active, military age women are rare (Meyer et al 1992). In September of 1992 the American Urologic Association endorsed the use of biofeedback for urinary incontinence as a safe and effective procedure.

(4) Preliminary Studies:

(a) A pilot study on active duty females revealed that the incidence of urinary stress incontinence during the standard PT test approaches 30%.

(b) A study performed on active duty airborne trainees at Ft. Benning Georgia isolated ten subjects who had no incontinence before airborne training but demonstrated genuine stress incontinence after airborne training. This incontinence was fond to be the result of pelvic floor injuries sustained during the rigors of airborne training.

2. BODY (METHODS):

a. The study's overall design was presented in the detailed summary above. Patient flow and experimental design are summarized in Figure One on the next page.

b. Determination of number and availability of subjects: The small pilot studies of incidence performed by the investigator showed that about one third of the female soldiers participating had significant problems with urinary incontinence. A power analysis based on formulae and tables in Cohen's (1988) book on statistical power analysis indicates that about 1,000 female soldiers will have to complete the surveys to be able to differentiate the effects of parity, severity and type of incontinence, and MOS. The number of patients requiring biofeedback was based on the difference between untreated controls and women treated with biofeedback in the small studies reported in the status section.

c. Data analysis: Data from the survey will be analyzed using discriminate analysis to determine weather specific patterns of answers, especially MOS, predict incontinence. Each question will also be analyzed separately using a Mann-Whitney "U" test. Differences in amount of urine lost between the before and after treatment(s) tests will be evaluated using a one-tailed, two way, repeated measures analysis of variance where the repetitions are the urine lost tests and the second direction is biofeedback or no biofeedback. A third repeated measure will evaluate changes from after biofeedback to after either surgery or medication. Different tests will be run on soldiers with stress and urge incontinence so differences in the data will not be mixed.

3. PROGRESS TO DATE: 87 Questionnaires have been filled out to date. Thirteen are currently in treatment and an additional six have completed the urodynamic tests and are ready to begin treatment.

Figure One: STUDY DESIGN AND PATIENT FLOW

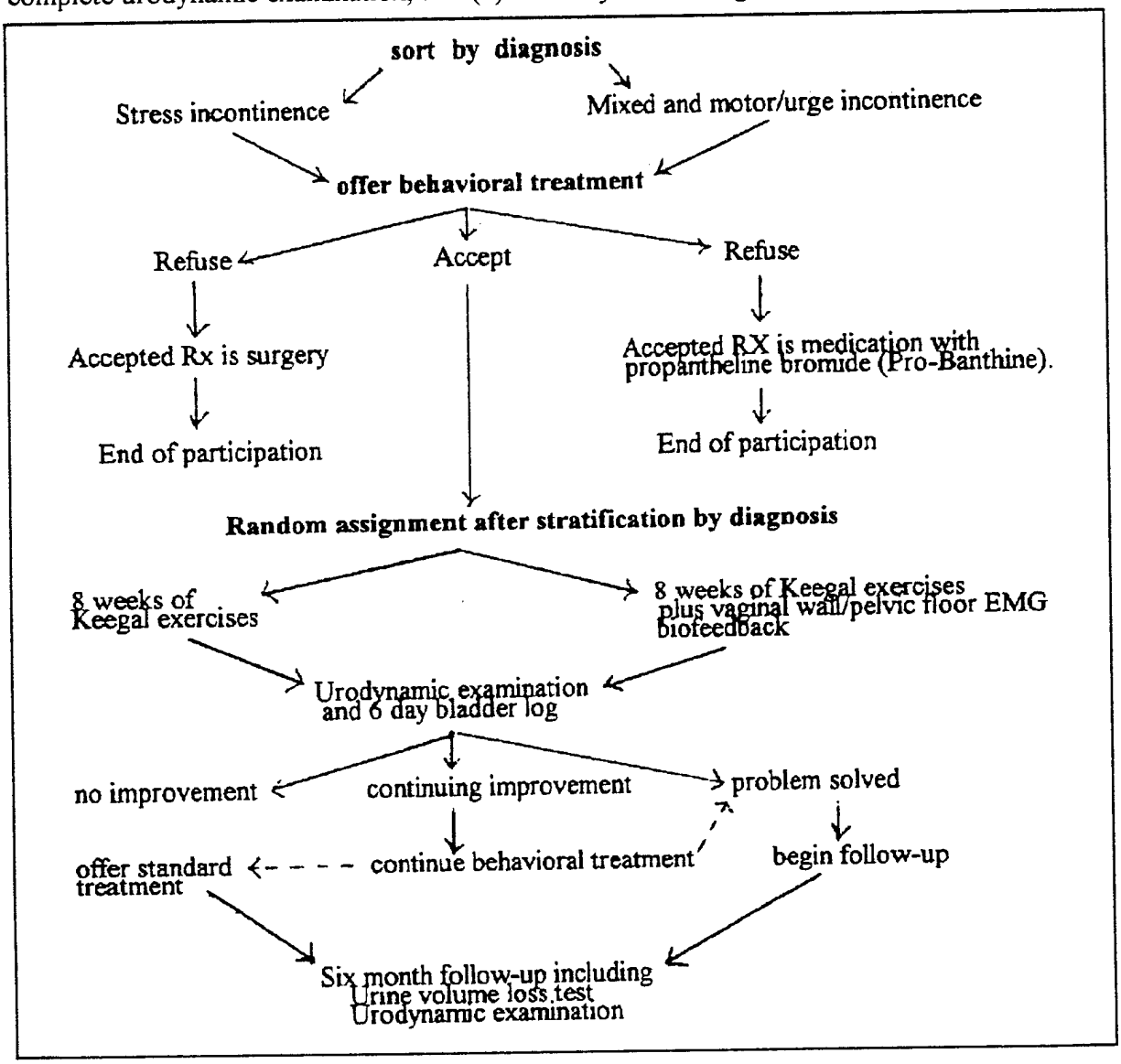
1,000 female soldiers assigned to participating units asked to fill out an anonymous questionnaire about (1) any problems with exercise related urinary incontinence and (2) its impact on their ability to perform their duties in both garrison and field environments.

About 300 soldiers reporting significant urinary incontinence problems

About 700 soldiers not reporting significant incontinence problems

End of participation

Each will be offered diagnosis of the problems with: (1) a urine volume loss test and (2) a complete urodynamic examination, and (3) a six day bladder log



a. Evaluations of the performance impact and treatment of exercise induced urinary incontinence among female soldiers. In these studies completed during the first six months of the project, we passed out questionnaires regarding incontinence during exercise to all female participants in the standard Physical Training (PT) exercise from one unit. From that evaluation of the subjects identified from these questionnaires we have made the following observations:

(1) Urinary stress incontinence appears to be the most common form of urinary incontinence among active duty females.

(2) A surprising number of the subjects are nulliparous.

(3) A number of the subjects only have urinary incontinence to a problematic degree during the luteal phase of their menstrual cycle.

(4) Many subjects are able to determine when the event which precipitated the incontinence occurred. Performing side-straddle-hops during the luteal phase of the menstrual cycle has been the most common event identified.

(5) Certain MOS's(i.e., Cooks and Petroleum technicians) appear to present an unusually high incidence of urinary incontinence. Both these MOS's involve heavy lifting, and physical training is not emphasized to the degree it is in combat support units.

(6) Non-surgical approaches, including biofeedback or Keegal exercises appear to be more effective than previously reported in alleviating both stress and urge urinary incontinence.

b. Plan for the balance of the study based on the first six months:

We have largely overcome the difficulties initially encountered in obtaining permission to study all females in particular units.

By studying all females in several units we should be able to accurately determine the incidence of urinary incontinence in the female soldier.

A portable multi-channel cystometric unit recently appeared on the market. The new technology will allow us to determine the function of the bladder during the actual athletic event which precipitates the urinary incontinence. The could provide much valuable information.

Once we have provided questionnaires to several combat, and combat support units, we should have no problem in obtaining adequate numbers of volunteers to complete our objectives.

The effectiveness of both the standard surgical interventions for stress urinary incontinence, and medical treatments for urge incontinence will be evaluated on those subjects who have not achieved satisfactory results from biofeedback/Keegal or Keegal exercises alone.

Those subjects will also enable us to study the side effects of standard incontinence medicines on female soldiers during the PT test and other work involving the need to perspire.

A significant number of subjects have completed the first phase of this study, and with the anticipated number of subjects entering the study, we anticipate no problems in meeting our objectives with regards to the record phase of the study.

4. INTERIM CONCLUSIONS: Although our work is still in progress and many of our observations have not been analyzed statistically, we have accumulated sufficient evidence to substantiate the following hypotheses:

a. About one-third of female soldiers have at least moderate exercise induced urinary incontinence. More than ten percent have urinary incontinence problems to the extent that it interferes with job performance, and negatively effects job satisfaction.

b. Exercise related urinary incontinence produces a significant impact upon female soldiers' ability to perform their exercises and tasks.

c. Urinary tract biofeedback, combined with exercise training for stress and urge urinary incontinence is sufficiently effective for at least one-half of the female soldiers.

When completed, this work should add considerable insight as to the extent of pelvic floor injuries in the female soldier, as well as better define the most effective treatment for those disorders.

Perhaps most importantly, this research has defined several factors which appear to be related to pelvic floor injuries.

Information gained from this study will prove valuable in the prevention of pelvic floor injuries in the female soldier.

5. FUTURE PLANS:

a. **Incidence of training injuries vs. phase of the menstrual cycle**: The most important finding to date was totally unexpected. This is the relationship between incontinence and the luteal phase. If ligaments are actually being significantly stretched/weakened during this phase, a huge rate of training injuries would occur during this phase relative to the others. This must be investigated immediately as it has profound economic and health implications for military training. We are beginning a pilot study of this problem in the next few weeks and will apply for funding this November for a full study (if the pilot results warrant it) relating all training injuries among female soldiers to the phase of their menstrual cycle.

b. **Ambulatory recording of urodynamic functioning during training:** This study has already confirmed the importance and prevalence of the problem but we do not understand how it develops. Until we understand the mechanisms causing the problem, we can't develop preventive measures. We will apply for funding to perform a longitudinal study of female Army trainees who will wear ambulatory urodynamic recorders during active periods of their training to determine what is happening to bring about incontinence.

c. **Test of the ability to utilize biofeedback for urinary incontinence among female soldiers in normal clinical troop treatment arenas:** This study has also already shown that biofeedback is very effective for treatment of urinary incontinence among female soldiers. We need to perform a larger study designed to bring this treatment from the clinical laboratory into general practice and to determine its effectiveness in the normal clinical / troop clinic environment. We will apply for funding for this study in November.

d. **Determination of the incidence and treatment of fecal incontinence among female soldiers**: As word of this study has spread through a variety of clinical areas including troop medical clinics, Ob-Gyn, family practice, and Orthopedics, health care providers have begun asking their female soldiers about fecal incontinence as well as about urinary incontinence problems. Although it appears to be somewhat less frequent, it is a significant problem which has been unrecognized at this time. This November, we will propose a study virtually identical to the current study to investigate incidence and treatment of the problem.

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