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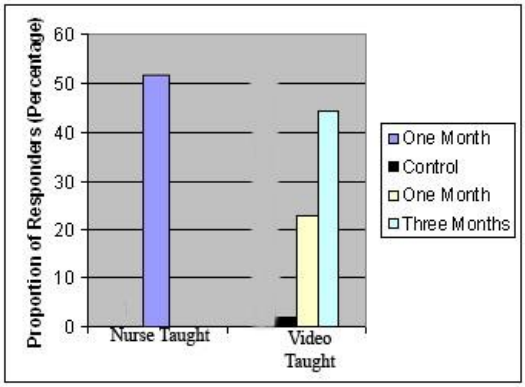
SHORT TERM RESPONSE TO KNACK THERAPY (NO DEDICATED MUSCLE STRENGTHENING) FOR TREATMENT OF INCONTINENCE

Hypothesis / aims of study

The Knack treatment for urinary incontinence involves teaching women to contract their muscles in anticipation of expected leakage. It does not include dedicated muscle strengthening exercises. This "quick therapy" has demonstrated effectiveness in reducing leakage on standing stress test when evaluated in the clinic but is untested in daily life. This abstract summarizes three phases of a project designed to evaluate Knack effect in daily life: Phase 1) demonstrating short-term efficacy with personalized instruction, Phase 2) a randomized controlled trial of video instruction, and Phase 3) long-term efficacy at 1-year post-intervention.

Study design, materials and methods

In Phase 1, 64 incontinent women completed a pre- and post-test trial in which Knack instruction was provided individually by a nurse practitioner as part of a prospective clinical trial. The nurse taught how and when to use the Knack and provided feedback on technique through digital palpation and by demonstrating the woman's own pelvic muscle contraction when coughing on perineal ultrasound. In Phase 2, 111 incontinent women completed a single-blinded randomized controlled trial of Knack instruction as provided by video. All women had a pelvic examination during which a nurse asked them to contract their pelvic muscles, including on ultrasound, but did not provide instruction in using them to reduce urine leakage. The treatment group watched a video about Knack therapy while the control group watched a video on food pyramid instruction. Both videos were approximately 10 minutes long. The video included actresses portraying when to use the Knack in Knack such as sneezing, coughing, on arising, and to suppress urge situations sensations triggered by running water or arriving home. The video included an ultrasound showing use of the Knack to stabilize the also during a cough maneuver. Phase 3 recyles the control group bladder back into the study to receive the Knack intervention after their 1- women visit. Responders from all three phases will be followed to 1-year. month we defined positive response is more rigorous than is typically The way intervention trials for incontinence. We used strict *a priori* criteria, used in Positive response required 50% improvement on at least 2 of 3 as follows. incontinence episodes on diary, leakage volume on quantified measures: stress test, and self-reported improvement using a scale of 0 – 100%. standing



Results

In Phase 1, Knack instruction provided by a nurse resulted in 51% of the sample being categorized as a positive responder at 1-month follow up. In the RCT (Phase 2), at 1 month the control group (diet video) showed a 2% response rate whereas the treatment group (Knack video) showed 23% (p = .007). This initial response rate to the Knack video improved to 44% at 3-months, without any additional intervention. (See figure). Phase 3 to determine persistence of effect at 1-year post-intervention is in analysis phase.

Interpretation of results

Using stringent objective outcome criteria, half of women who learned the Knack from the nurse have a 50% reduction in their incontinence episodes during normal activities at one month. When Knack instruction is provided by video the response rate is lower at 1 month (23%), but similar at 3 months (44%) compared to a 2% response rate in control women at 1-month. These improvements occur without dedicated muscle strengthening exercises as part of the intervention, demonstrating that skill in using a muscle contraction to stop incontinence is effective at rates that are similar to those reported from muscle strengthening trials.

Concluding message

Although personalized instruction in the Knack elicits a quicker response than video instruction, the exciting potential is that a brief video could be viewed, for instance on YouTube, with remarkable potential as a wide scale public health intervention.

Specify source of funding or grant	**NIH/ORWH P50 HD44406**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**IRBMED University of Michigan**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**