Changing practice on the basis on evidence? CFA Melbourne 2011

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7 stages in the career of a medical innovation McKinlay- 81, Wall-01

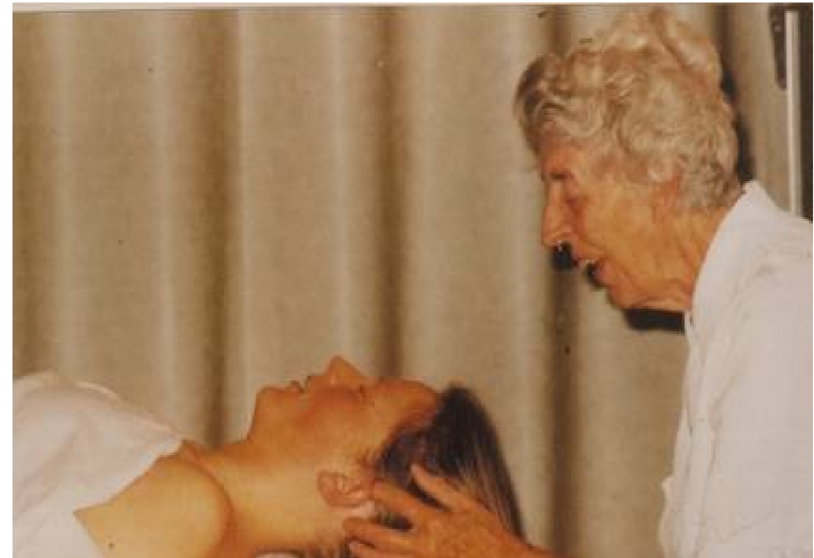
1. Promising report, clinical observation, case report, short clinical series
2. Professional and organizational adoption of the innovation
3. The public accepts the innovation – state or third party pays for it
4. Standard procedure – into textbooks (still no critical evaluation)
5. **RCT !**
6. Professional denounciation
7. Erosion of professional support, discredit

Voltaire:

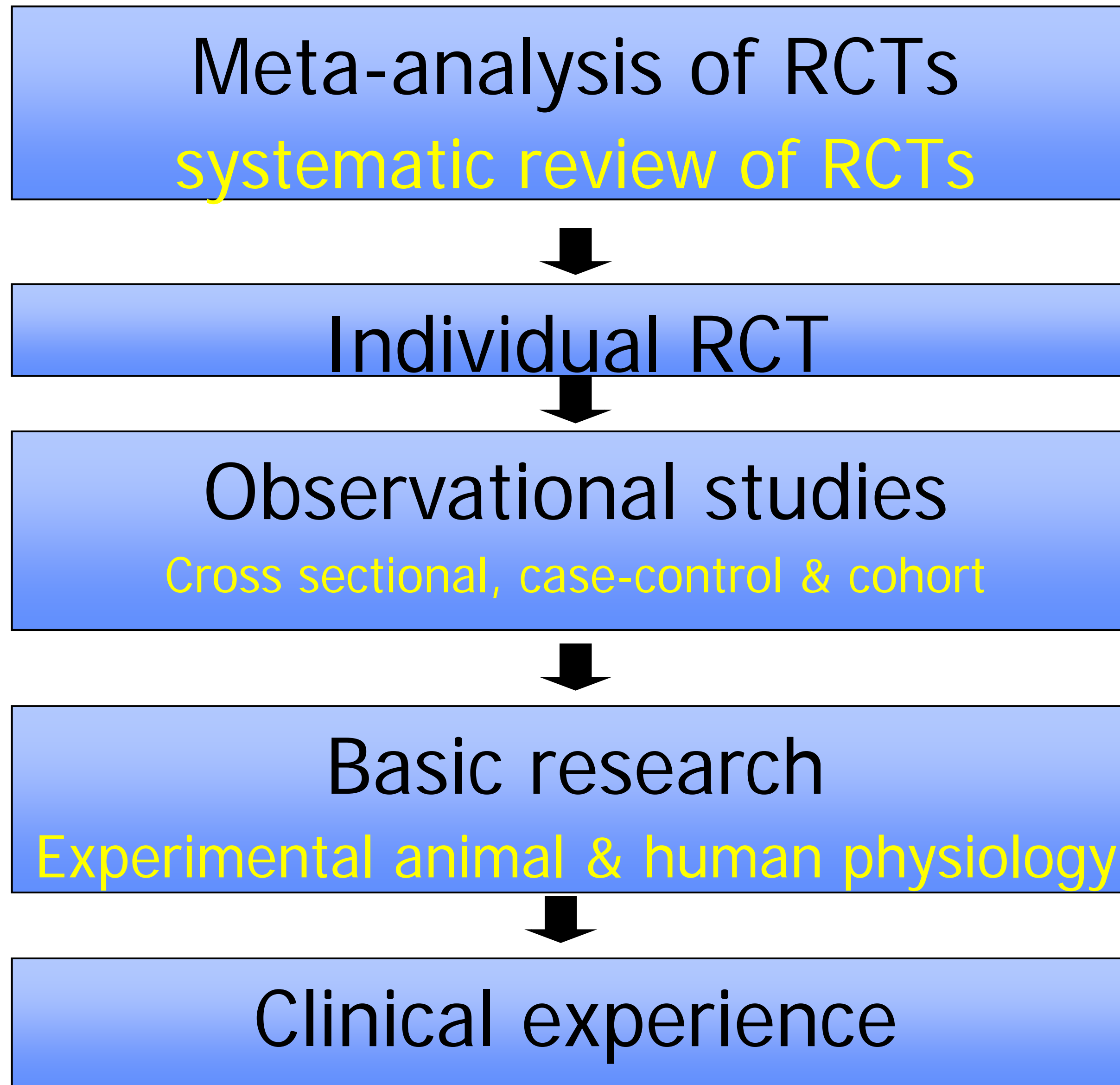
"The art of medicine consists of amusing the patient while nature cures the disease"

Evidence based medicine Sackett 1996

- "Evidence based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about care of individual patients"



Hierarchy of Evidence (for effectiveness)



INTERNAL VALIDITY

- To which extent the changes observed are caused by the experiment/ intervention/ physiotherapy and not by confounding factors

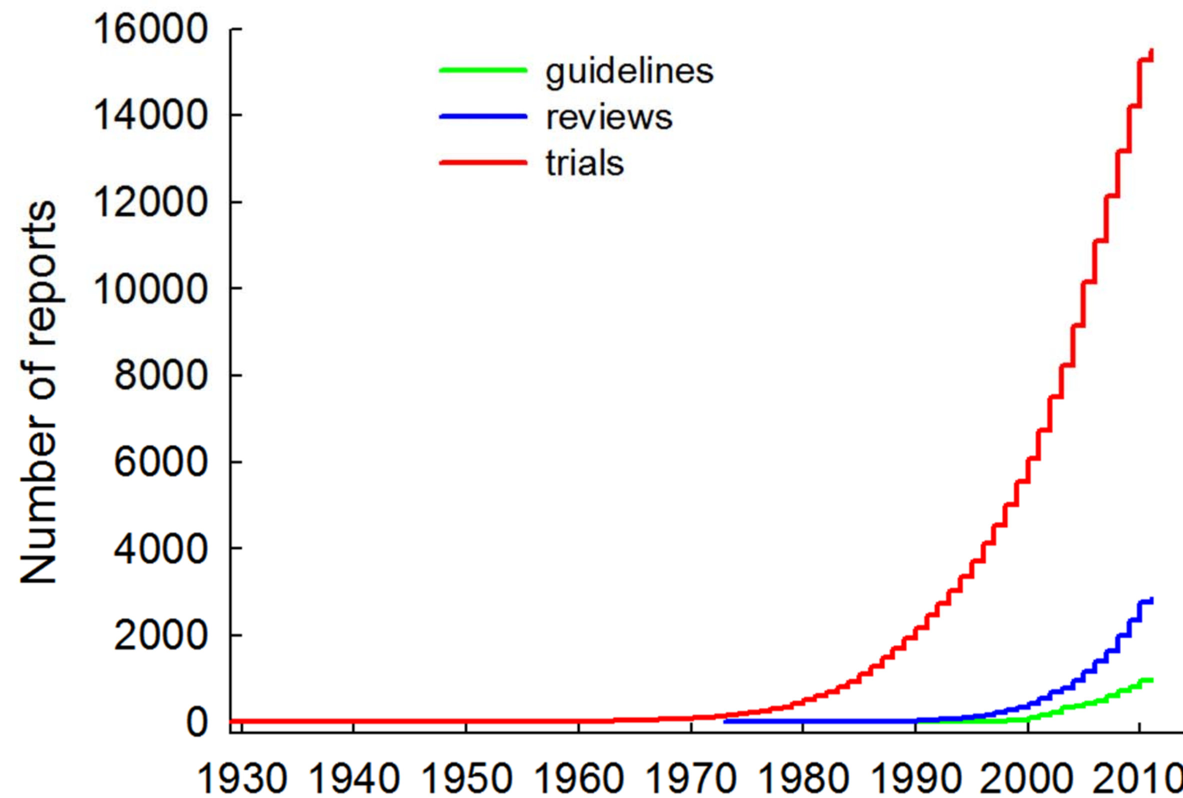
WHY RCTs for intervention studies? INTERNAL VALIDITY (Thomas & Nelson-96)

- History
- Maturation
- Testing
- Instrumentation
- Statistical regression
- Selection biases
- Experimental mortality
- Selection maturation interaction
- Expectancy

Historical development

- Clinical experience, no data
- Theory- Movement science, data
  - Small experimental studies (neurophysiology, education, pshycology, biomechanics)
- Clinical trials – RCT, data with effect size

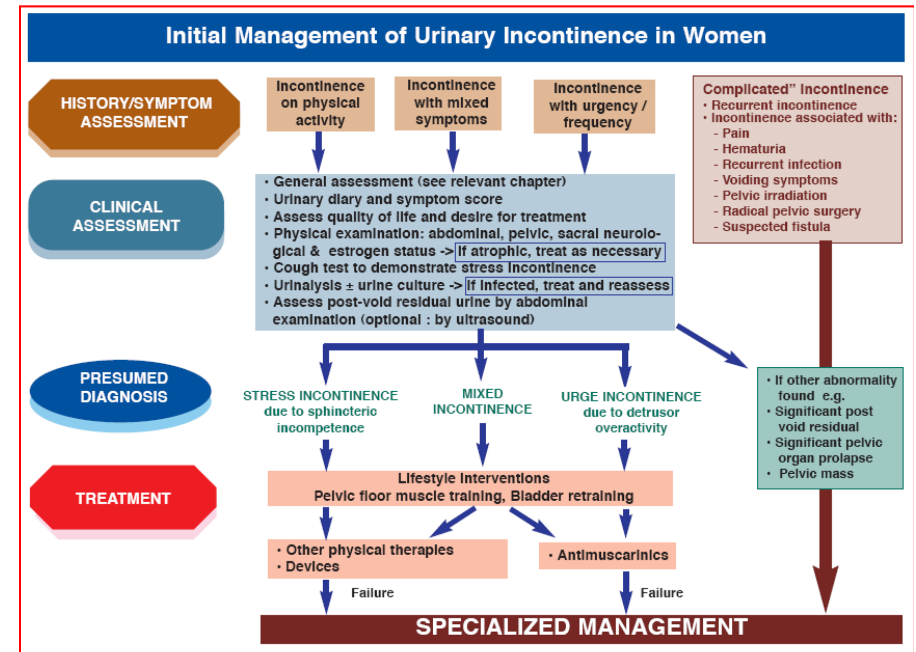
There are RCTs available for decision making PEDro June-11



Consensus/recommendations UI

- Systematic reviews
- Cochrane Library 2001, 2010
  - > 60 RCTs

- NCC-WCH -06: Level A: <u>High quality studies.</u> Supervised PFMT for at least 3 months first line treatment for SUI and mixed UI
- ICI -99,-02,-05 -09: Level 1, Grade A
- Imamaura et al -10

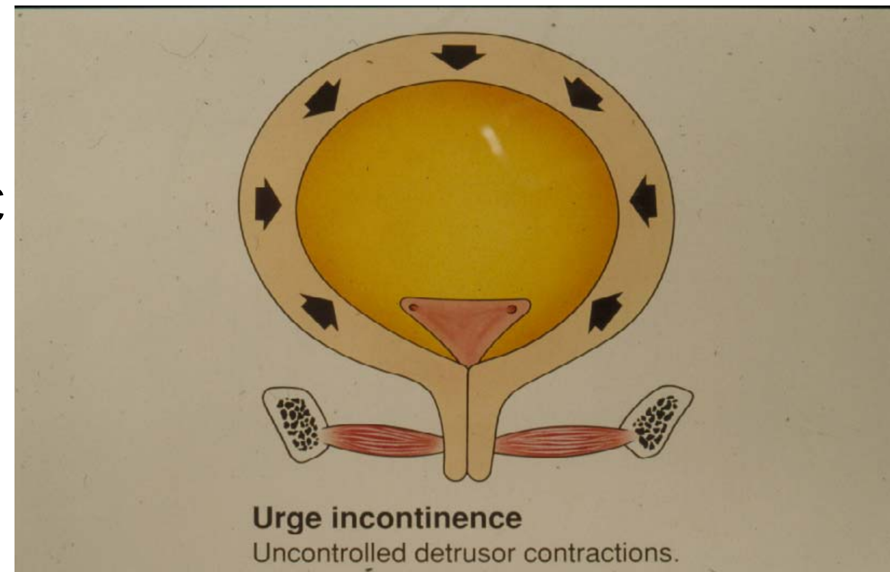


Can PFMT cure (pad test) SUI?

- Henalla et al 1989: 65% cured/ >50% reduc
- Bø et al 1990: 60% positive UCP
- Henalla et al 1990: 50% cured/ >50% reduc
- Ramsay et al 1996: 70/77% cured
- Glavind et al 1996: 58% cured
- Wong et al 1997: 55% cured
- Bø et al 1999: 44% cured
- Aksac et al 2003: 75/80% cured
- Mørkved et al 2001: 69/50%, 67/65% cured
- Dumoulin et al 2004: 70/70/0% cured
- Felicissimo et al-2010: 37/35% cured

Evidence for PFMT in OAB

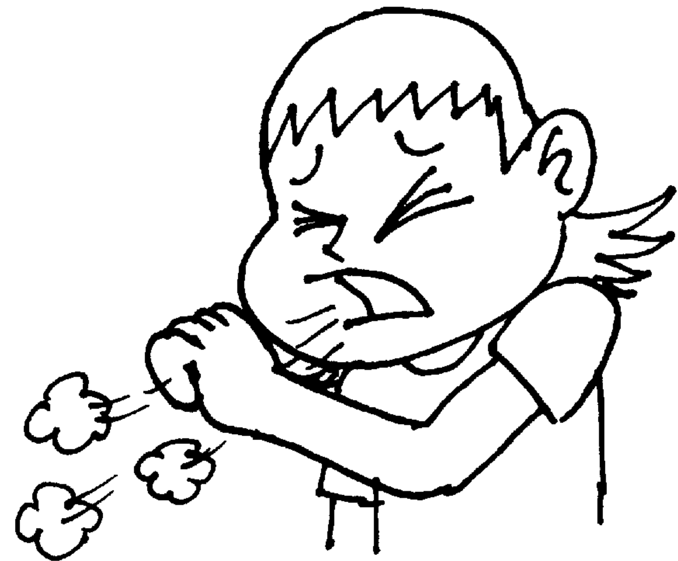
- 4 RCTs (Berghmans et al -02, Wang et al -04, Millard et al -04, kafri et al -07)
- 2 with no effect
- Pathophysiology is not clear. Theory and basic research support possible effect
- Question on content and dosage of intervention
- Need for further RCTs



The "Knack" Miller et al 1998

- 27 women. Mean age 68.4 (5.5) years with mild to moderate SUI
- 1 week of voluntary PFM contraction before and during cough
- Results:

Redused urine loss from medium/ deep cough by average 98% and 73%

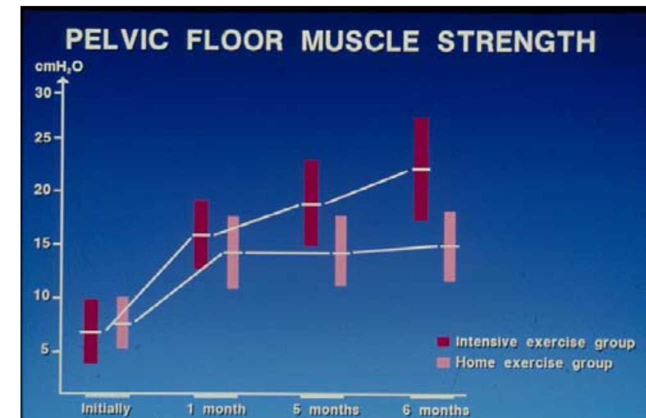


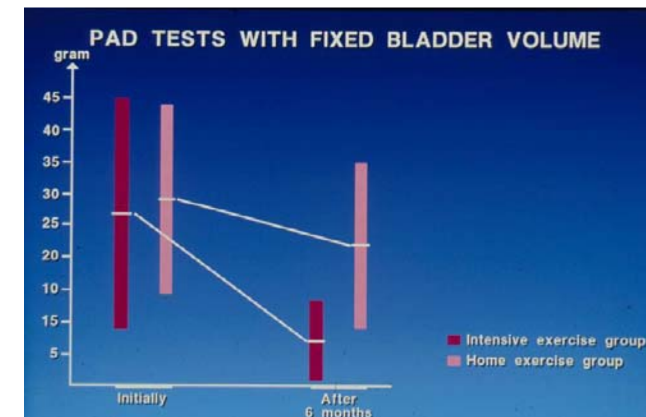
PFM training protocols for SUI

- Only 4/36 RCTs described ”skill training” (voluntary contraction during cough)
- Type of exercise: PFM
- Intensity ?: 3-40 sec
- Repetitions: 8-12 x 3/day - >200
- Frequency: every day
- Duration: 6 weeks-6 months
- Adherence: few reports

More is better than less…

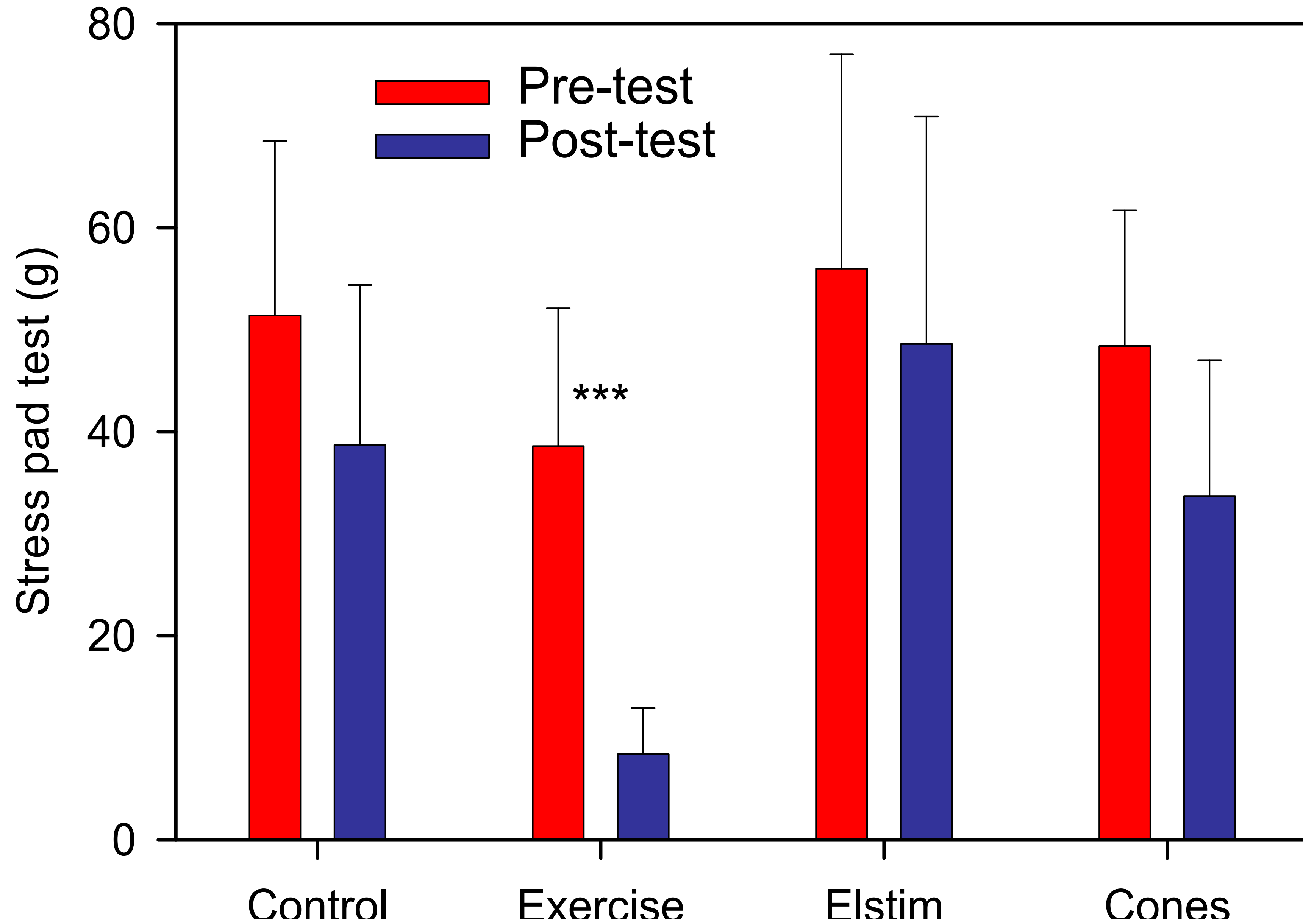
- Bø et al -90
- Nygaard et al -96
- Glavind et al -96
- Wong et al -97
- Gallo et al -97 (only adherence)
- Goode et al -03
- Sugoya et al -03 (motivational device)
- Zanetti et al -07
- Konstantinidou et al -07



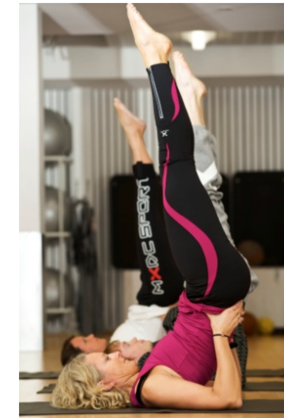


Evidence for different methods of PFMT ICI -09, Cochrane -01

- PFMT
  - Alone — level A
  - With resistance device — no add. effect
  - With vaginal cones — " "
  - With biofeedback — " "
- Electrical stimulation — ?
- Combination — no add. effect


Bø et al, BMJ-99
Pre-test
Post-test
Stress pad test (g)
80
60
40
20
0
***
Control
Exercise
Elstim
Cones

"Alternative" methods to PFMT?

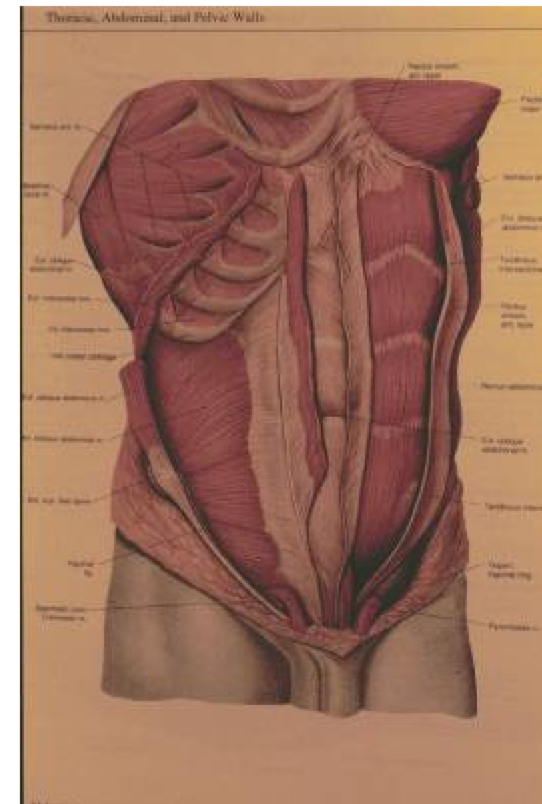


New model for PFM-training

Sapsford: Physiotherapy 2001, Manual Therapy 2004

- "Abdominal muscle training to rehabilitate the PFM may be useful in treating urinary and fecal incontinence" Sapsford&Hodges -01

- "The findings of this study indicate that exericse of the abdominal muscles may be benficial in maintaining PFM coordination, support, endurance and strength" Sapsford& Hodges-01



PFMT versus PFMT + TrA

Dumoulin et al, Obstet Gynecol 2004

- Single blind RCT at least 3 months postpartum, 8 weeks intervention, once a week with PT, 5 days a week at home
  - A: PFMT + el.stim, n= 20
  - B: A + TrA, n= 23
  - C: Control (massage!), n= 19
- Results:
  - 70% cure rate in both treatment groups. No cure in control, but improved QoL (disease specific)
  - no additional effect of adding TrA to PFMT

Retraining diaphragmatic, deep abdominal and PFM co-ordinatated function" Hung et al 2010

- Single blind RCT. History of SUI or MUI, 4 month intervention following vaginal palpation
  - Alternative: 8 visits with PT: diaphragmatic breathing, tonic activation of TrA and PFM, muscle strengthening of TrA/ PFM/ IO, functional expiratory patterns like coughing /sneezing, impact activities such as jumping and running
  - PFMT: Oral instruction and usual information on UI, PFMT and bladder hygiene

Results Hung et al 2010

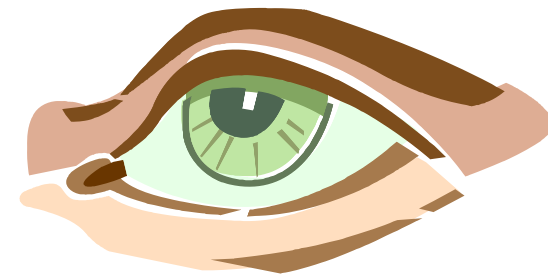
- Sign more patients subjectively cured/improved in "alternative" group
- No difference change in pad test, number of voids, number of leaks, PFM strength (vaginal squeeze pressure)
- Sign diff between groups at post-test in "number of activities affected" and "avoiding activity due to needing a toliet"

Limitations Hung et al 2010

- Significantly more with urgency in "alternative" group
- Amount of leakage and numbers of leaks at baseline: mean 0 g and 0!
- "Alternative" includes PFM contractions
- PFMT is far from optimal
- Huge difference in dosage and attention
- Conclude that this is promising for those who cannot accept palpation!!!?

"Paula method of circular muscle exercises" Liebergall-Wischnitzer IUJ, 2005

- Theory: activity of distant sphincters affects other muscles
- Method: Single blind RCT, 59 women with SUI or MUI
  - Paula: Individual 45 min/weekly including PFMT, daily 15-45 min at home for **12 weeks**
  - PFMT: group training 30 min/weekly for **4 weeks,** daily 15 min at home, phoned by PT every second week



"Paula method" results

- Both groups sign reduction in pad test: Paula: mean 5.4g (95% CI:2.08-8.65, $p=0.002$)
- No change in PFM strength (perineometer)
- QoL ↑ 8.6 points out of 110, $p=0.02$ in Paula only
- LIMITATIONS
  - Protocol difference, dosage + attention
  - Paula includes PFMT
  - NO COMAPRISON BETWEEN GROUPS

Can the "Paula method" facilitate PFM contraction?

- Experimental study with 4D perineal ultrasound, power calculation
- 17 pregnant or postpartum women
- Results
  - Sign reduction of LH area and muscle length only after PFM contraction
- Conclusion: No facilitation of PFM during constriction of the mouth Bø et al -11

- Experimental study with surface EMG
- 34 healthy nulliparous women
- Results
  - No activation during Paula
  - No additional effect of adding Paula to PFM
- Conclusion: No activation during Paula Resende et al-11

Pilates Culligan et al 2010

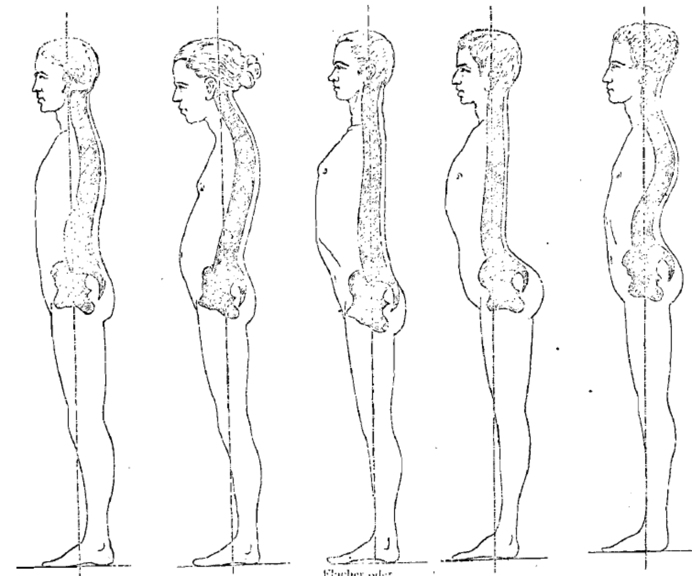
- Following vaginal palpation and assessment of PFM strength: 1- h individual sessions twice weekly for 12 weeks
  - Pilates including instruction of PFM contraction
  - PFMT including biofeedback, vaginal manipulation, massage, neuromuscular re-education, manual therapy focusing strictly on the pelvic floor (!?)
- Results: no difference in change of PFM strength 6.2 (SD 7.5) versus 6.6 (SD 7.4) cm H_2O
- Conclusion: results are encouraging and may eventually lead to widespread use of Pilates-based exercise programs to treat and prevent pelvic floor dysfunction (?)
- 26% of Pilates and yoga instructors report UI Bø et al-11
- Pilates and Yoga exercise without PFM precontraction descended bladder neck of 0-17 mm Baessler & Junginger -10

Take a deep breath!?

- Increased PFM EMG activity in expiration (n=7) Hodges et al-07
- Pos correlation PFM strength & forced expiratory flow, cs study Talasz et al-10
- Disorders of breathing & continence associated with LBP Smith et al 06,09
- Meaning what?

Improve your posture!

- «Poor posture can lead to dysfunction of the pelvic floor» Carriere -06
- «Non-optimal strategies for posture, movement and/or breathing create failed load transfer which can lead to UI» Lee et al-08
- «Global postural re-education», better results than PFMT Fozzatti et al -10
  - non-randomized
  - different dosage & attention



Staffel 1889

Reduce weight!

- RCT: N=88 overweight / obese: liquid diet: 60/15% in weekly UI episodes Subak et al -05
- RCT:N=338 overweight /obese, mean age 53, BMI 36. NB!booklet on UI Mean weight loss 7.8/ 1.5 kg. Decrease in UI: 47/ 22% Subak et al -11

20 CITY TIMES Wednesday, December 20, 2006

Chubby children in London plan lean Christmas in the hope of being rewarded well if the diet works

CHRISTMAS PICKINGS will be leaner this year for several overweight children in London primed to fill up on healthy food such as Brussels sprouts and fruit instead of extra helpings of turkey stuffing and pudding.

"Last year, in my stocking I had lots of chocolates. This year I just want toys and healthy stuff," said 10-year-old Charlie Siggins, who meets with 10 other overweight and obese children twice a week to learn about nutrition and exercise.

Classmate Brooke Ivers, 11, chipped in: "I'm not going to eat too much junk."

Bad diet and inactivity is pushing up obesity rates in England, where 19 per cent of boys and 18 percent of girls aged 2 to 15 were

A passenger waits for a delayed flight at Heathrow airport's terminal four in London's Heathrow airport

pr91651 www.fotosearch.com

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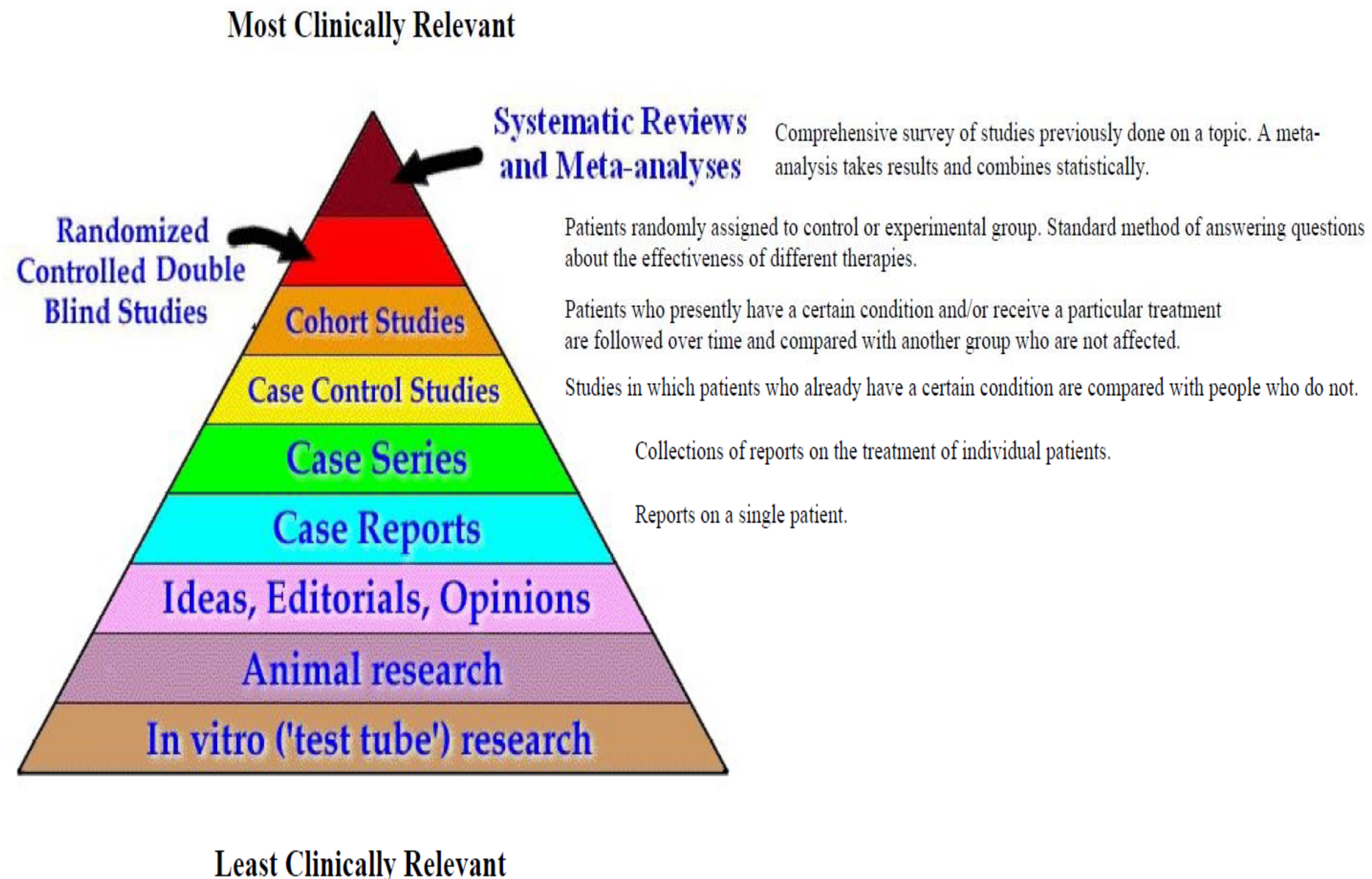
Do we change PT practice from:

- Theory?
  - It is still the core for change!
  - Even more dangerous today, because it is "research based"

- RCT?
  - It is difficult to make changes!
    - Negative results
    - Practice that is different from mainstream

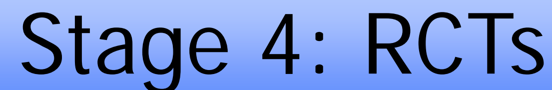
When and how should new therapies become clinical practice?

Physiotherapy, Bø & Herbert 2009



Protocol for implementation of new therapies

Bø & Herbert, Physiotherapy -09



Stage 6: Dissemination

Recommendations for effective strength training Pollock et al, ACSM 1998, ACSM 2006, Haskel 2007

- specificity
- 8-12 slow velocity close to maximum contractions (fewer repetitions better to optimize strength and power)
- 3 sets / day
- 2-3 (4) days a week
- > 5/6 months

Morphological changes Brækken et al, Obstet Gynecol -10

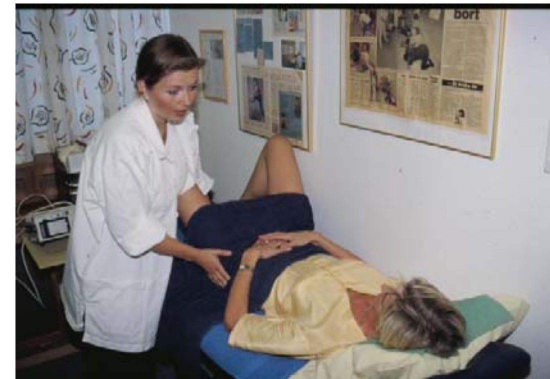
- RCT (n=109) Diff between PFMT and control
- ↑Muscle thickness: 1.9 mm (95% CI: 1.1-2.7) 15.6%
- ↓Hiatal area: 1.8 cm^2 (95% CI: 0.4-3.1) 6.3%
- ↓Muscle length: 6.1 mm (95% CI: 1.5-10.7) 4.2%
- ↑Pos bladder neck: 4.3 mm (95% CI: 2.1-6.5)
- ↑Pos rectal amp: 6.7 mm (95% CI: 2.2-11.8)

- ↓Hiatal area and muscle length during straining, indicating automatic function and increased PFM stiffness?

Keys to success

- Thorough individual assessment of correct contraction
- Information and motivation
- Teach precontraction before rise in IAP!
- Supervized individual *or* group training with encouragement of MVC
- Should there be follow-ups?

- Weak interventions will be very costly if they do not work!



How does PFMT work? Bø, Int Urogyn J - 04, Elsevier-07

- Concious pre-contraction before and under increase in abdominal pressure (the "KNACK")
  - EVIDENCE!
- "Functional" training
  - NO EVIDENCE, BUT COMMON IN PT PRACTICE?
- Strength training
  - STRONGEST EVIDENCE!
- Indirect training of the TrA?
  - NO EVIDENCE, BUT ***some*** PTs LOVE IT!
- "Alternative methods"
  - NO EVIDENCE

Thank you for your attention!