Effectiveness of Training Primary Care Physicians in Physical Activity Counselling

Proposal for a Cluster Randomized Controlled trial

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U.S. Preventive Services Task Force

- The USPSTF found insufficient evidence to determine whether PA counseling in primary care settings leads to sustained increases in PA among adult patients
  - variable (low) quality
  - mixed results

Limitations of previous studies

- About half were not RCTs
- Contamination between arms was frequent
- F-UP rates were often not mentioned or low (40-60%)
- Reported outcomes were often derived from post-hoc analysis
- PA levels were not consistently defined
- PA level was almost always self-reported

Objectives

- To investigate whether patients of physicians who are trained in PA counseling increase their PA level more than patients of physicians who received a control training session
- To assess in both arms of the study the content of the intervention by interviewing recruited patients

Methods

- Cluster randomised controlled trial
  - Unit of Randomization = physicians (and their practice)
  - Remotely generated randomization
  - Stratification by age and gender
  - Unit of Analysis = patients
- Study population (two-level)
  - Swiss family physicians
  - Their sedentary patients

Methods (continued)

- Inclusion criteria for patients
  - Age 15-69
  - < 30 minutes of moderate physical activity per week
    - Confirmed by monitoring of daytime physical activity during one week with an electro-mechanical monitor
- Exclusion criteria for patients
  - Debilitating medical condition
  - Known unstable cardiac condition
  - Not able to understand French/German
  - Expected to leave the region

Methods (continued)

- Recruitment of patients:
  - Consecutive, during 1½ week within each practice
    - Physicians see an average of 100 patients a week and about 1/7 approached patients should be eligible and willing to participate
  - Control and Intervention practices will be screened in parallel to control for a potential seasonal effect on physical activity level

Description of the intervention

- Physicians allocated to the physical activity intervention will follow a 2-4 hours multi-component training curriculum (+/- e-learning) enclosing:
  - Theory on health-enhancing PA
  - Theory on the TTM
  - Skills for motivational interviewing
  - Role playing
  - Use of booklets, and prescription forms
  - Use of referral to a physical activity counselor
  - Suggestions for organizational optimisation

Exposure assessment

- Attendance of physicians to the training sessions will be documented
- Extent and adequacy of counselling will be assessed by interviewing patients with the help of a check-list
  - Score of compliance = the mean number of items that have been addressed by each physician among their patients

Outcome assessment

- Total weekly energy (TWEE) expenditure will be assessed with an electro-mechanical device
- When compared with the « Gold Standard » of portable metabolic measurements, data obtained with this method have demonstrated promising citerion validity
- Participants could be blinded to its motion sensoring function to limit the potential for a « Hawthorne » effect

Statistical analysis

- Difference in mean TWEE will be compared using:
  - A general linear regression model
  - Adjustment for a limited set of other pre-defined covariates (e.g. baseline differences in PA, academic affiliation [yes/no], solo-practice [yes/no])
  - An additional term to model the random-effect due to clustering of data within practices
- Intention-to-treat analysis
- Sensitivity analysis will be used to handle missing data

Sample size calculation

- n1=n2=640 (2x32 clusters of 20 patients)
- Assumptions
  - Alpha=0.05
  - Power=0.80
  - Mean TWEE interv@1yr=247 (42) kcal/kg/wk [Elley 2003]
  - Mean TWEE control@1yr=236 (45) kcal/kg/wk [Elley 2003]
  - n2/n1=1.00
  - Mean cluster size m=20
  - ICC=0.05 [Elley 2005]
  - Attrition rate=0.25

Strengths

- Use of an objective measure of PA
  - Smaller risk of reporting bias
- Partial blinding of participants should reduce the risk of co-intervention
- Contamination risk is limited by the cluster design
- Equal contact condition is respected by using a control training session
- Good external validity and sustainability

Limitations

- The primary outcome is rather distal
  - A dilution of the effect may occur along the chain of events
- The study may be underpowered to detect small differences in secondary outcomes (BMI, BP, HRQL)

Timeline, budget, and dissemination

- Pilot phase: 2007
- Ethics board submission: Sept 2007
- Recruitment of physicians and patients: 2008
- Follow-up: 2009
- Data analysis and report: March 2010
- Budget: Need further elaboration
- Intended dissemination:
  - peer-reviewed publication
  - meeting presentations
  - developements in the field of CME