

# Evaluating Effectiveness of Complex Interventions: Challenges in using RCTs

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## Aim



Exchange and debate about the challenges of experimentation in identifying what works in complex social interventions

# Content

## Content



1. Complex Intervention
2. Subject of Evaluation
3. Evaluation Question
4. Challenges
5. Method
6. Results
7. Discussion
8. Conclusion

# Complex Intervention

Full text available online  
Free articles see bmj.com

## RESEARCH METHODS & REPORTING

### Developing and evaluating complex interventions: the new Medical Research Council guidance

Peter Craig,<sup>1</sup> Paul Dieppe,<sup>2</sup> Sally Macintyre,<sup>3</sup> Susan Mitchie,<sup>4</sup> Irwin Nazareth,<sup>5</sup> Mark Petticrew<sup>6</sup>

Evaluating complex interventions is complicated. The Medical Research Council's evaluation framework (2000) brought welcome clarity to the task. Now the council has updated its guidance

Complex interventions are widely used in the health service, in public health practice, and in areas of social policy that have important health consequences, such as education, transport, and housing. They present various problems for evaluators, in addition to the practical and methodological difficulties that any successful evaluation must overcome. In 2000, the Medical

#### SUMMARY POINTS

The Medical Research Council guidance for the evaluation of complex interventions has been revised and updated

The process of developing and evaluating a complex intervention has several phases, although they may not follow a linear sequence

Experimental designs are preferred to observational designs in most circumstances, but are not always practicable

Understanding processes is important but does not replace evaluation of outcomes

Complex interventions may work best if tailored to local circumstances rather than being completely standardised

Reports of studies should include a detailed description of

## Features of complex interventions

- ❖ Behavioral, non-pharmacological
- ❖ Number of groups or organizational levels targeted by the intervention
- ❖ Number and difficulty of behaviors required by those delivering or receiving the intervention
- ❖ Number of interacting components
- ❖ Longer causal chain with weak links between the intervention and the health outcome
- ❖ Degree of flexibility/tailoring permitted

*MRC guidance on complex interventions*  
(Craig et al. 2008)

# Complex Intervention



- Vaccination as a example of a simple intervention



- Health behavior change interventions: health education, clinical health care, psychotherapies, health promotion.
  - Health promotion is carried out by and with people, not on or to people. It improves both the ability of individuals to take action, and the capacity of groups, organizations or communities to influence the determinants of health.

Jakarta Declaration (WHO, 1997)

# Intervention “classes in movement”

## Goal

- To encourage teachers to build physical activity into their daily teaching routine
- To improve motor skills and emotional and social well-being in school children aged 8 to 11 years

## Target Group

- Teachers in primary schools in Lower Austria
- Children 8 to 11 years

## Method

- Multiplier approach (teacher)
- 20 months duration
- 20 hours “one to-one-teacher training”
- 16 hours “teachers group training”: theoretical backgrounds and practical didactical techniques

## Implemented since 1994

Intervention and evaluation funded by the Lower Austrian Health and Social Fund





# Intervention “classes in movement”

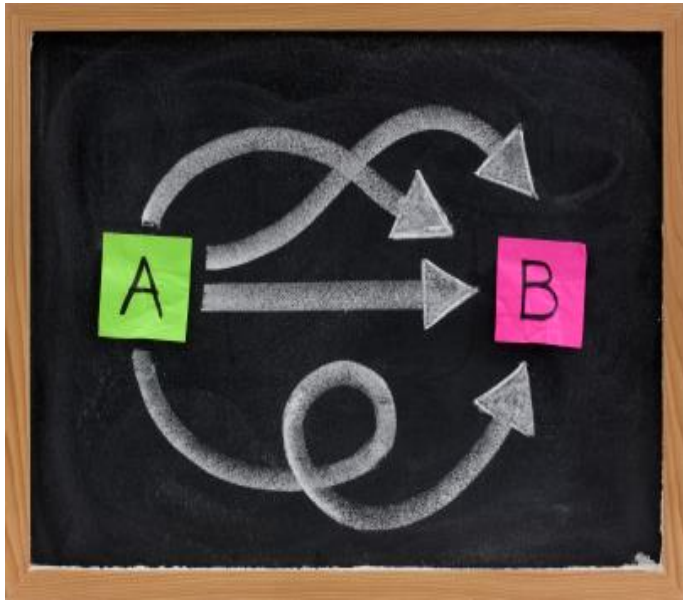


# Research Question

**Does it work?**



# Complex Intervention



Classes in Movement has all of the features of a complex intervention and it is implemented in a complex social system (school)

# Research Question

**Does it work?**

# Challenges

## Main Challenge

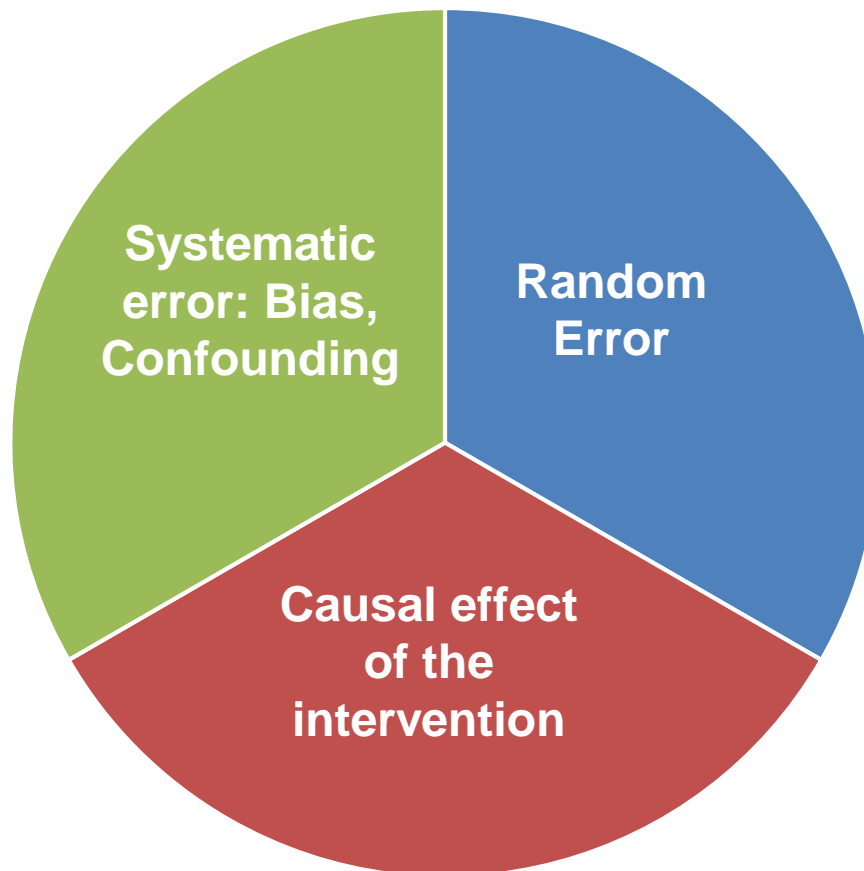


To capture the effectiveness of  
complex interventions in  
complex systems

# Challenges

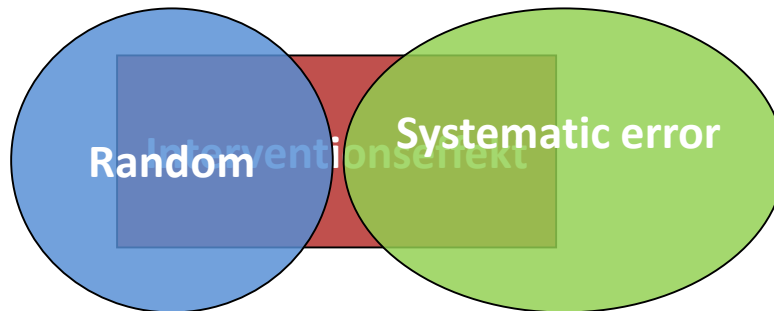
## How to capture effectiveness

- ❖ Results of effectiveness evaluations consists of various components



# Challenges

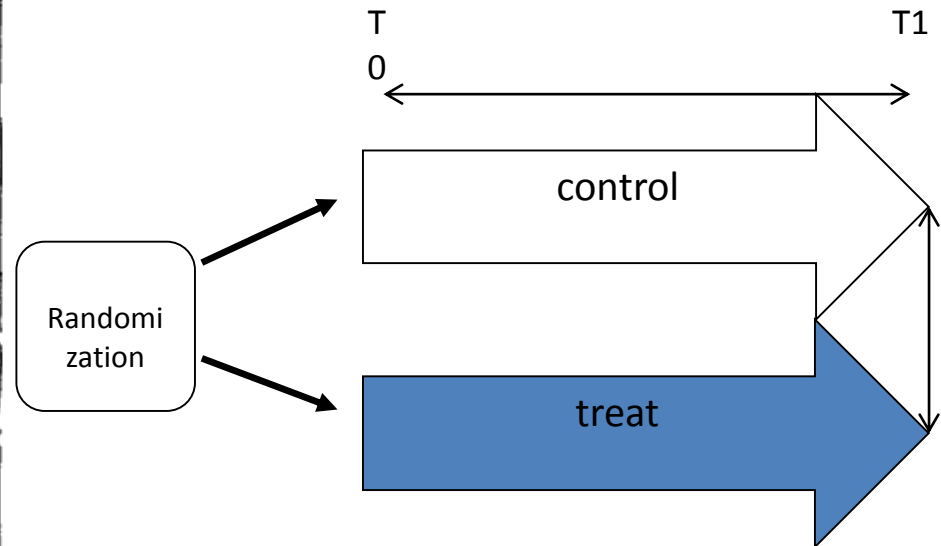
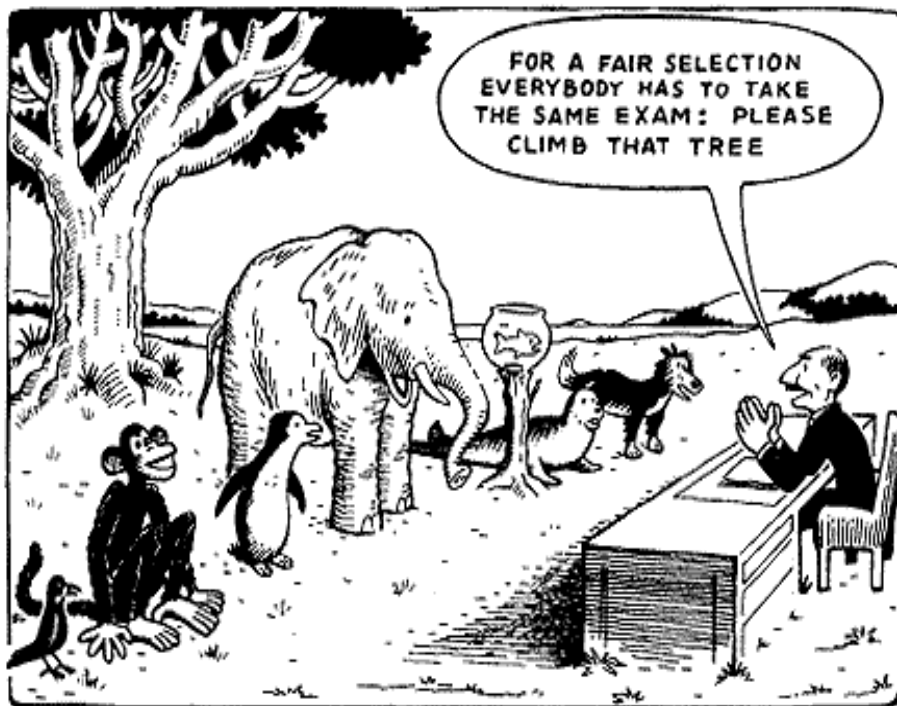
Credibility/validity



# Challenges

## Randomised allocation minimises selection-bias

- ❖ Non-biased selection of participants into experimental and control groups has been recognized as the way forward in the reliable and valid quest to discover “what works” (Davies et al 2000, Schünemann et al., 2017)



RCTs are the most rigorous way to evaluate effectiveness of interventions.

(Oakley, Strange et al. 2006)



# Challenges

To RCT or not to RCT ?



- ❖ **Standardization:** “Requirement for interventions in different sites to be standardized or look the same.”  
Nutbeam 1998, WHO 1999 WHO European working group on health promotion evaluation
- ❖ **Randomization:** Randomization should always be considered because it is the most robust method of preventing selection bias. (Craig et al. 2008)
- ❖ **Context-intervention mechanism:** “RCT preclude context level adaptation which is essential for health promotion interventions to work” (Rychetnik, Frommer et al. 2002)
- ❖ **Interpretation of study results**  
Evaluation failure vs. program failure (Rychetnik, Frommer, Hawe, & Shiell, 2002)  
External Validity: To whom does it apply?

# Method

## Mixed Method Approach:

Cluster randomised controlled trial with an embedded process evaluation



1. Logical model  
“Swiss model for outcome classification in health promotion and prevention”:(Spencer et al., 2008)  
*Workshops with “Intervention-team”*
2. Baseline assessment
3. Random allocation of classes
4. Intervention / waiting control group
5. Process evaluation
6. Follow up assessment
7. Analyses & Conclusions

# Method

| Outcomes  | Instrument   |
|---|--|
| <b>Emotional and social quality of life in classroom:</b> |  |
| Emotional quality of life in classroom                    | Rauer W, Schuck K-D. FEESS 3-4 (2003)                  |
| Attitude towards school                                   | Rauer W, Schuck K-D. FEESS 3-4 (2003)                  |
| Feeling of being accepted by the teacher                  | Rauer W, Schuck K-D. FEESS 3-4 (2003)                  |
| <b>Emotional and physical experiences:</b>                |  |
| Psychological quality of life                             | The KIDSCREEN group Europe. KIDSCREEN (2006)           |
| Physical quality of life                                  | The KIDSCREEN group Europe. KIDSCREEN (2006)           |
| Moods and emotions  | The KIDSCREEN group Europe. KIDSCREEN (2006)           |
| Protective factor "sense of coherence"                    | Bettge S. (2004)                                       |
| <b>Coordinative motor skills:</b>                         |  |
| Coordination with precision                               | Bös et al. Deutscher Motorik-Test (2008)               |
| Coordination under time pressure                          | Bös et al. Deutscher Motorik-Test (2008)               |
| Spatial orientation skills                                | Prätorius et al. Kinder-Koordinationstest (2007)       |
| Complex reaction ability                                  | Prätorius et al. Kinder-Koordinationstest (2007)       |
| Kinesthetic differentiation ability                       | Prätorius et al. Kinder-Koordinationstest (2007)       |
| <b>Self-reported physical activity</b>                    |  |
| Physical activity during the school breaks                | Kowalski et al. PAQ-C (2004)                           |
| Enjoyment of physical activity                            | Moore et al. Measuring enjoyment of in children (2009) |
| <b>Ability to concentrate</b>                             | Brickenkamp et al. d2-R. Test (2010)                   |

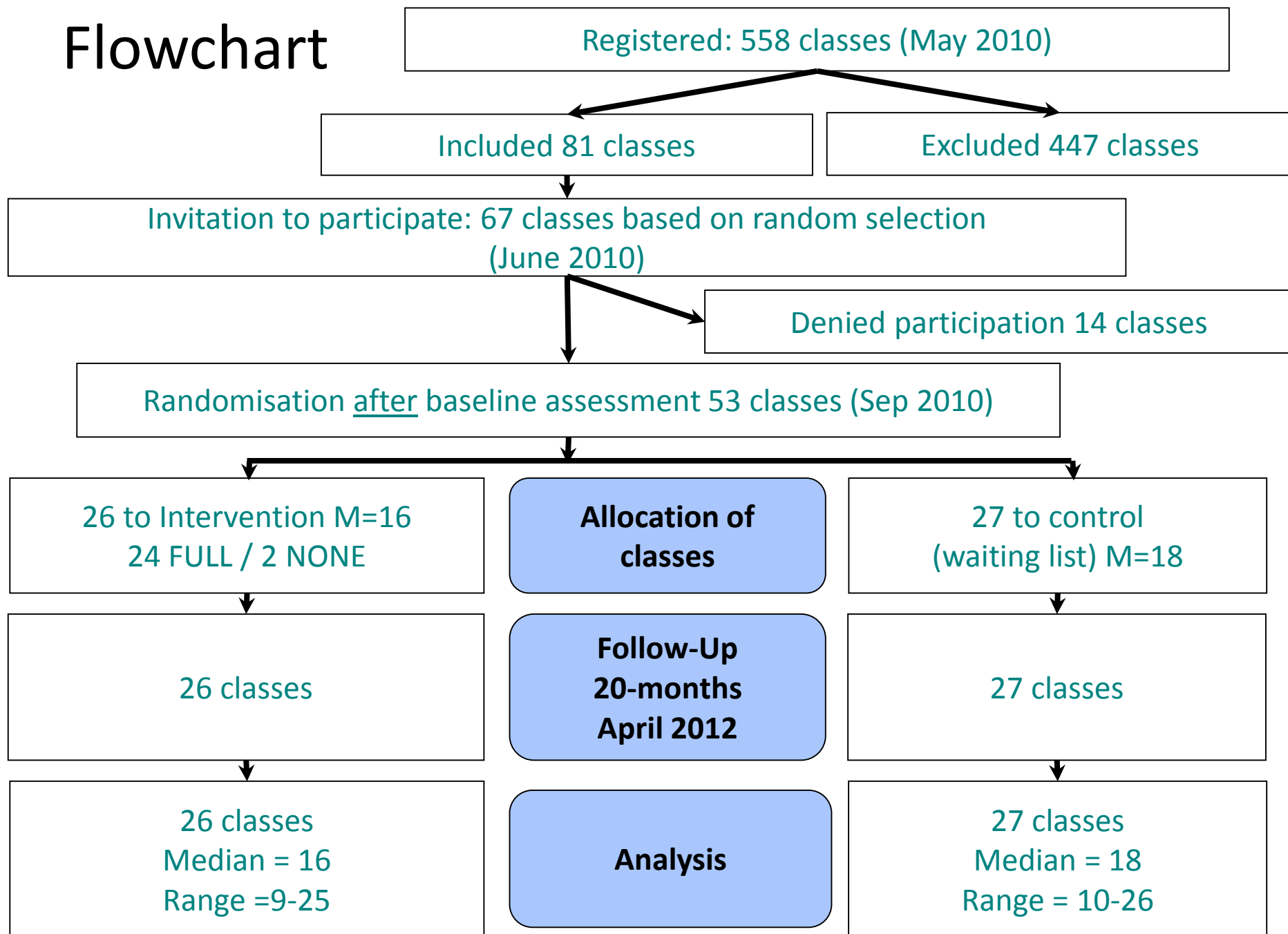
# Method

## Considering context



- **Schools:** size of school and class, presence of other health promotion measures
- **Teacher:** attitude and expectation, years of service, previous experience, teaching load, gender, self-efficacy creating healthy and positive learning environment
- **Children:** gender, age and socioeconomic status, current physical injuries

# Flowchart



# Method

## Process evaluation:



- ❖ Documentation of on-the-job training  
*trainer documentation*
- ❖ effect perception of change in teaching practice  
as movement pauses, moving breaks, active and  
moving lessons... :  
*51 (24 treatment, 27 control) retrospective teacher  
questionnaires and 24 telephone interviews (treatment);  
8 trainer interviews, 49 parent questionnaires*
- ❖ Teachers perception, attitude acceptance of the  
intervention:  
*24 retrospective teacher interviews*



# Results

## Process Evaluation

- ❖ Positive perception of the intervention (teacher, trainer and parents)
- ❖ Central elements of the intervention:
  - ❖ Trainer: 20h “one-to-one teacher training” & 16h “teachers group training”
  - ❖ Teacher: “one-to-one teacher training”
- ❖ Challenges:
  - ❖ Trainer: maintaining teacher motivation, only 20h teacher training, no termination criteria
- ❖ Perception of effects:
  - ❖ Most teacher reported a positive change in classroom practice towards more physical activity
  - ❖ Largest changes in the design of exercise and physical education lessons

# Method

## Quantitativ Analysis

- ❖ Multilevel growth modelling (The R environment using *nlme* package)
- ❖ Three analytic levels
  - ❖ Measurement occasion
  - ❖ Individual (several co-variants were included)
  - ❖ Class
- ❖ Missing data: full information maximum likelihood (FIML) estimation under the missing at random (MAR) assumption
- ❖ Significance level of all analyses was chosen at  $\alpha = 0.05$

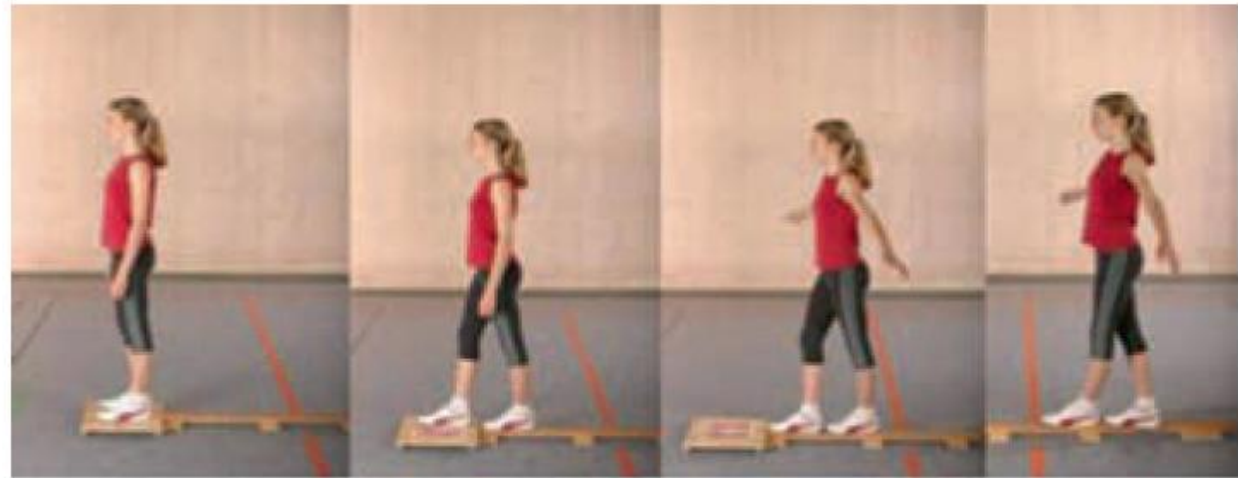
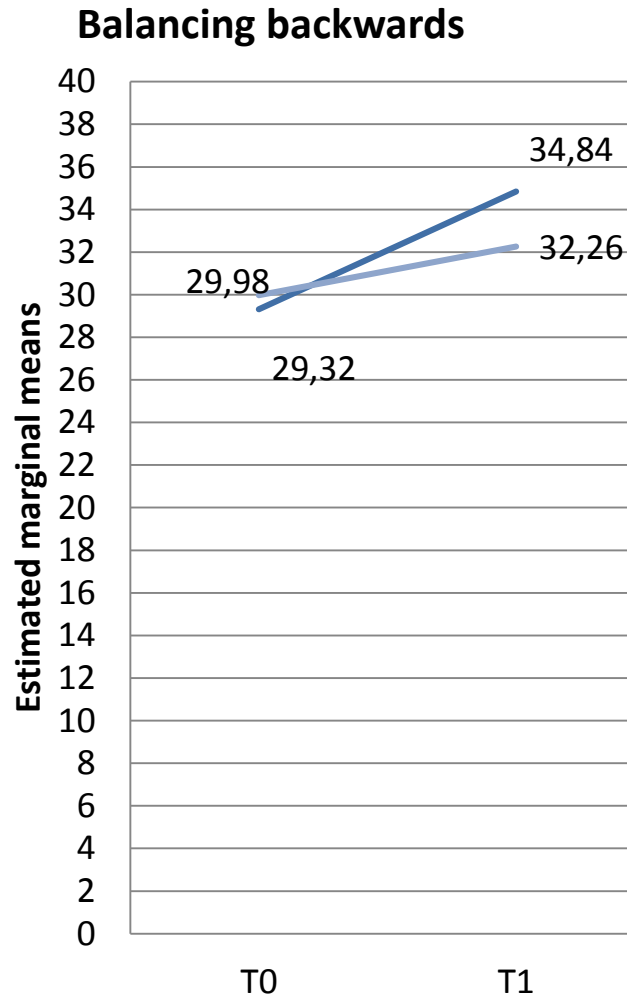
# Results

Correlation between intervention and outcomes (Multilevel growth model)<sup>#</sup>.

|  | $\beta$ | ICC class <sup>§</sup> | 95% CI <sup>+</sup> |       | p Value | Score range  |
|--|---------|------------------------|---------------------|-------|---------|--------------|
|  |         |                        | Lower               | Upper |         |              |
| <b>Emotional and Social Experience at School</b> |         |                        |                     |       |         |              |
| Classroom climate (primary outcome)              | -0.02   | 0.451                  | -0.16               | 0.12  | 0.78    | 0-3          |
| Attitude towards school                          | -0.10   | 0.115                  | -0.26               | 0.06  | 0.22    | 0-3          |
| Feeling of being accepted by the teacher         | -0.03   | 0.093                  | -0.13               | 0.07  | 0.55    | 0-3          |
| <b>Physical activity</b>                         |         |                        |                     |       |         |              |
| Physical activity during the school breaks       | 0.20    | 0.116                  | -0.09               | 0.49  | 0.2     | -3 - +3      |
| Enjoyment of physical activity                   | 0.02    | 0.014                  | -0.08               | 0.12  | 0.66    | 1 – 4        |
| <b>Well-being</b>                                |         |                        |                     |       |         |              |
| Psychological quality of life                    | 0.27    | 0.033                  | -1.62               | 2.16  | 0.78    | 20.7 – 73.2  |
| Physical quality of life                         | 1.11    | 0.016                  | -0.76               | 2.98  | 0.24    | 25.2 – 68.5  |
| Moods and emotions                               | 0.66    | 0.023                  | -1.74               | 3.06  | 0.59    | 16.5 – 70.2  |
| Protective factor “sense of coherence”           | 0.04    | 0.005                  | -0.16               | 0.24  | 0.66    | 1 – 5        |
| <b>Motor skills</b>                              |         |                        |                     |       |         |              |
| Coordination with precision                      | 2.58    | 0.085                  | 0.77                | 4.39  | 0.01    | 0 – 48       |
| Coordination under time pressure                 | 0.69    | 0.081                  | -0.47               | 1.85  | 0.24    | 5.5 – 62.0   |
| Spatial orientation skills                       | 0.46    | 0.044                  | 0.18                | 0.74  | <.01    | 0 – 10       |
| Complex reaction ability                         | -12.38  | 0.173                  | -17.72              | -7.04 | <.01    | 229.5 – 72.5 |
| Kinesthetic differentiation ability              | -0.32   | 0.032                  | -1.18               | 0.54  | 0.47    | 1.13 – 25.83 |
| Attention performance                            | 1.57    | 0.070                  | -2.12               | 5.26  | 0.4     | 6 – 135      |

# Results

## Coordination with precision

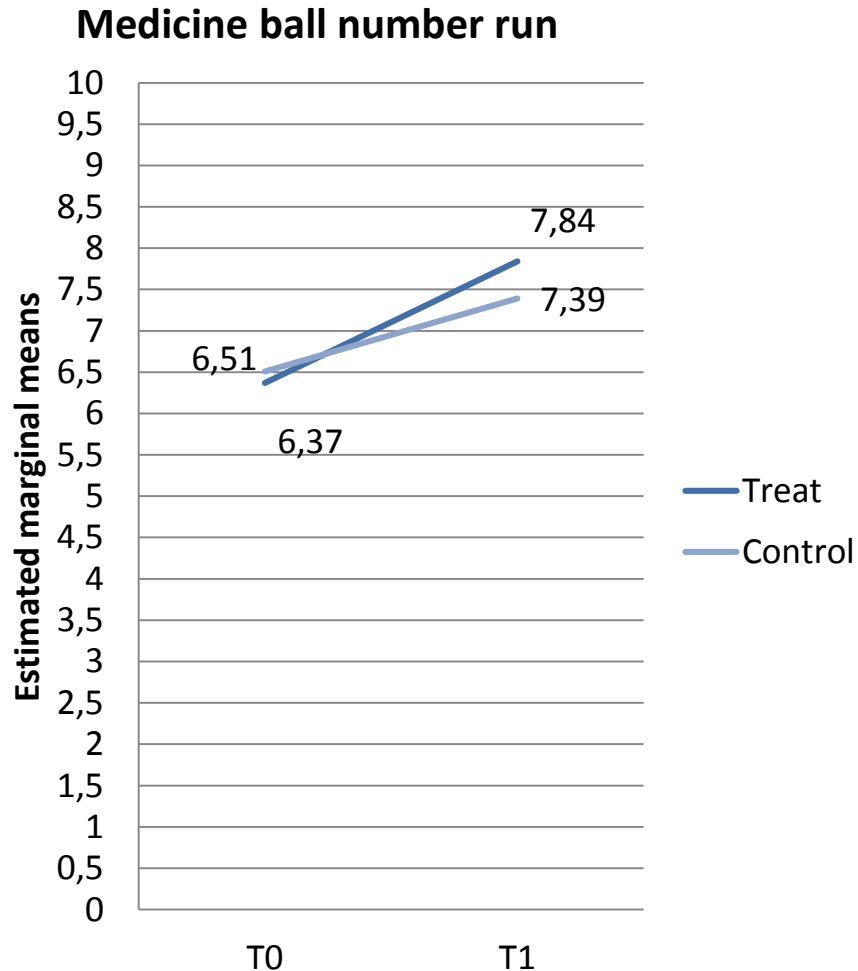


— Treat  
— Control

Additional 2.58 steps balancing backwards on a beam,  $p = 0.1$  (score range 0-48)

# Results

## Spatial orientation skills



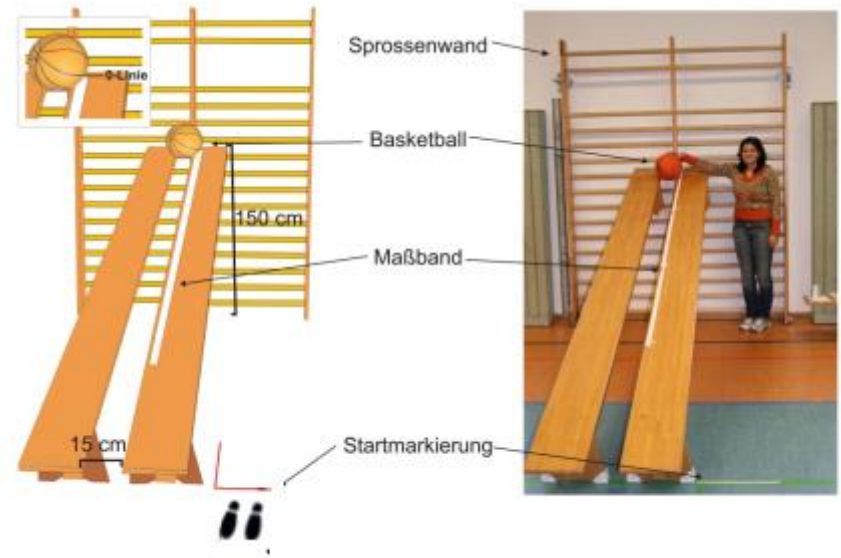
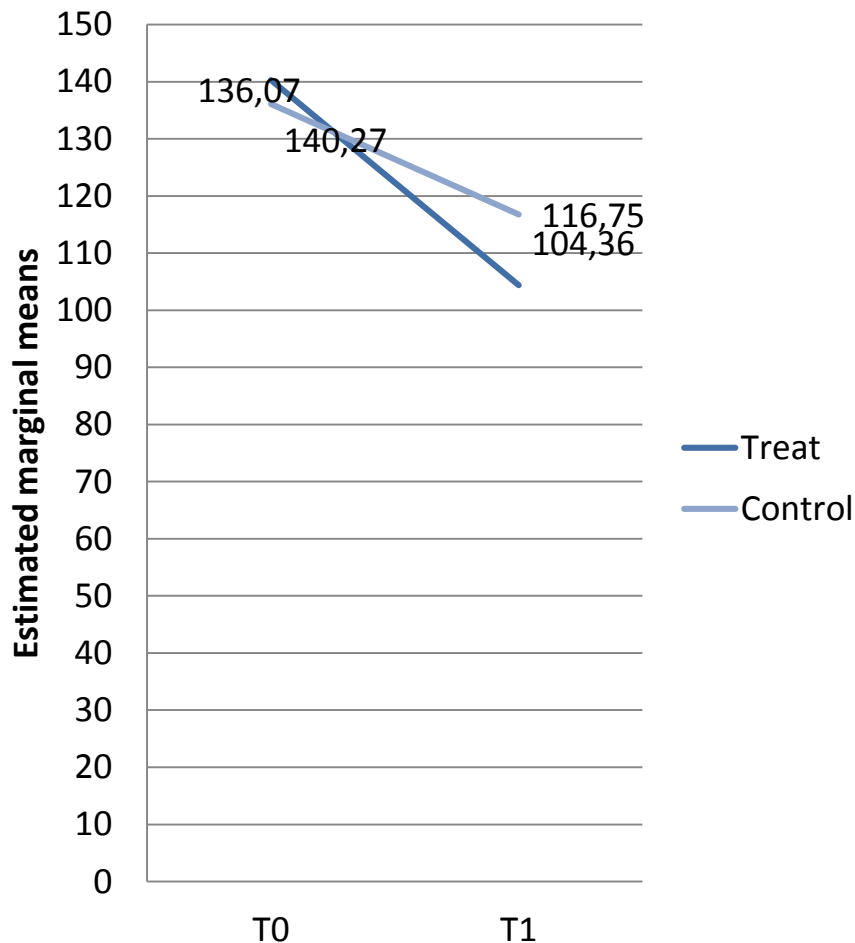
Measured: number of correct touches

Additional 0.45 points in “medicine ball number run”,  $p < .01$  (score range 0 – 10)

# Result

## Complex reaction ability

### Stopping the ball



Measured: distance a ball rolls until pupil can stop it by hand

12,39 centime difference  $p < .01$  (score range 229,5 – 72,5)



# Discussion

How do you interpret the results?



No effects in 12 of 15 outcomes  
Significant effect in 3 of 15 outcomes: all  
coordinative motor skills

## A) Intervention is ineffective

- *RCT*
- *Narrow confidence intervals*
- *80 % Power*
- ...

## B) Evaluation could not detect effects

- Measurement precision?
- Adequacy of outcomes?
- ...

# Discussion

## Adequacy of outcomes is related to the concept of complexity :

### Is complexity a property of ...

#### ... the intervention?

- ❖ Package of exactly describable elements
  - ❖ Common goal
  - ❖ Many mutually dependent and interacting components (e.g. Craig et al., 2008)

#### ... the social system?

- ❖ A complex of elements that are interconnected and interdependent, forming a structured entity.
    - ❖ Adaptive to their local environment (Shiell et al., 2008)
    - ❖ Non linear
    - ❖ More than the sum of the parts (Emergence)
- Z.B.: human bodies, schools, ...

Teachers are part of the complex system of school and part of the intervention

### ... intervention and the systems in which the intervention takes place?

Hawe, P. (2015) Lessons from complex interventions to improve health. *Vol. 36. Annual Review of Public Health* (pp. 307-323)

# Discussion

## Consequences of the systemic perspective of complexity



It needs endpoints that capture changes in the school system

- Class climate (Score Range 0-3)
- Relationship between school children and teacher (with and between)
- Role changes of teacher
- School agreements on health, physical activity...

**Outcomes on an individual level are not enough to capture complexity**

**As evaluation did not capture relevant system outcomes, conclusion of ineffectiveness would be exaggerated**

# Conclusions

- **Cluster RCT is a feasible way for rigorous effectiveness evaluation of complex health promotion interventions - in a controlled setting.**
  - Non-biased selection of participants and systems through randomization is possible
  - Baseline assessment prior to start of the intervention (blinding)
  - Embedded process evaluation (discrimination between failure of intervention theory and failure in implementation)
  - Theory based selection of outcomes
  
- **Distinguishing between intervention and evaluation failure is challenging**
  - Process evaluation alone is not sufficient
  - It needs a theory of change (intervention and the system it is implemented in) to guide the selection of adequate outcomes:
    - Which concept of complexity is adequate for choosing outcomes?
    - What are the active ingredients of the intervention?
    - How to identify active ingredients?

Are we catching the “right” butterfly?



- Both is necessary for evidence-informed decision making: methodological rigor AND adequate outcomes
- There are explicit criteria for judging the methodological rigor of an effectiveness evaluation, however specific methodological processes for selecting adequate outcomes are rarely explicitly reported.

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