Evaluation of implementation trials in fall prevention

Kilian Rapp
Klinik für Geriatrische Rehabilitation
Robert-Bosch-Krankenhaus Stuttgart

Bologna, 24.02.2016
Background

- High burden of falls
- We know evidence-based measures to reduce falls (efficacy)
- Under-supply of fall prevention measures in the community
- Need of a wide-scaled implementation trials for fall prevention

Objective of the presentation

- Options and limitations when evaluating implementation trials
  - Not theoretical considerations about implementation research
  - Experiences from real world projects/programmes
Process of generating evidence

- Evidence-based intervention
  - e.g. efficacy trial

- Implementation
- Dissemination
- Diffusion

Evaluation
- Pilot studies
- RCT
- (short/long-term) observational studies
- Projects without any evaluation
Determinants of implementation studies

- Implementation studies …
  - deal with complex settings, different interest groups, circumstances, environments …
  - are influenced by many different factors, measures, strategies …

- Evaluation of implementation studies has to consider the different determinants
Implementation research - 6 domains

1. Influencing factors
   1. e.g. beliefs, work load

2. Strategies
   1. a) professionals: e.g. education, participation, b) organisations: e.g. influence on processes / structures, c) monetary: e.g. incentives, d) regulative/legislative: e.g. laws

3. Effects / Impact
   1. Outcome evaluation
   2. Process evaluation
      1. Reach, adoption, maintenance
   3. Evaluation of structures

4. Theories

5. Ethical considerations

6. Methods
   1. Quantitative / qualitative
RBK-examples of implementation trials

1. Fall prevention in nursing homes (The Bavarian Fracture Prevention Study) – (2007-2010)

2. Schritthalten - aktiv älter werden in Reutlingen (2010-2013)

3. The osteoporotic fracture prevention programme in rural areas (OFRA) – ‘Trittsicher durchs Leben’ (running)

4. Implementation of the Otago exercise programme (planned application)
'Real world' examples (I)

- Fall prevention in nursing homes - The Bavarian Fracture Prevention Study (2007-2010)
From efficacy to effectiveness

- Efficacy study: Multifactorial fall prevention trial in 6 nursing homes
  - Reduction of falls by 44% and fallers by 30% (Becker et al. JAGS 2003)

- Does the programme work in daily practice?

- Introduction of the program in nursing homes in
  - Baden-Württemberg (10.7 million inhabitants; 1200 care homes) – started 2003
  - Bavaria (12.5 million inhabitants; 1400 care homes) – started 2007

- Implemented by a health insurance company

- Since 2003 about 2000 nursing homes have adopted the programme
Results (I)

Baden-Württemberg
- No reduction of femoral fractures

Rapp et al., JAGS 2010

Bavaria 2007

Characteristics of the study population

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nursing homes</td>
<td>N</td>
<td>256</td>
</tr>
<tr>
<td>Number of beds</td>
<td>Mean (SD)</td>
<td>94.4 (41.3)</td>
</tr>
<tr>
<td>Study population</td>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>2,892 (21.2)</td>
<td>6,828 (21.6)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>10,761 (78.8)</td>
<td>24,840 (78.4)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>Mean (SD)</td>
<td>84.3 (7.5)</td>
</tr>
</tbody>
</table>
Results (II)

Effect on femoral fracture incidence

<table>
<thead>
<tr>
<th></th>
<th>Femoral fractures, n</th>
<th>Total person-years</th>
<th>Femoral fractures/1000 person-years</th>
<th>HR (95% CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fall prevention program</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No (Control group)</td>
<td>917</td>
<td>22,450</td>
<td>41.0</td>
<td>1.00</td>
</tr>
<tr>
<td>Yes (Intervention group)</td>
<td>331</td>
<td>9,882</td>
<td>33.6</td>
<td>0.82 (0.72-0.93)</td>
</tr>
</tbody>
</table>

* Hazard rate ratio and 95% confidence interval adjusted for gender, age, number of beds (log) and level of care

First intervention year: reduction of hip fractures by nearly 20%

Becker et al., PlosOne 2011
Relative risk of femoral fractures between residents from intervention and control homes in the years before the start of the intervention (2001-2006) and in the year of the intervention (2007)
Considerations about the evaluation

- **Strategies** (external validity)
  - Legislative: nursing homes had to implement specific standards in fall prevention
  - Monetary incentive (exercise trainer over 6 months funded, …)
  - Education, processes

- **Influencing factors**
  - Work load, habits, age of nurses

Why did the implementation work in Bavaria but not in Baden-Württemberg?
  - Bavaria: commitment by signing a contract to participate; national nursing guideline on fall prevention in long-term care was published; educational process was more interactive; …
  - We did no (comparative) process evaluation

Why was publication a problem?
'Real world' examples (II)

Schritthalten - aktiv älter werden in Reutlingen (2010-2013)

- Population-based approach to promote safe mobility and reduce falls in older people
- Target population: community-living people 65+ in a medium-size town (110,000 citizens)
Objectives of the project

- Measures should influence risk factors for falls…
  - muscle strength, balance, cognition, environmental hazards, drug prescription, …

- Measures should …
  - …be focused on health promotion (shift from fall prevention to health promotion)
  - …cover different domains of health (e.g. muscle strength, balance, endurance, …)
  - …fit in daily life
  - …influence elderly people’s attitude (e.g. concerning physical activity in old age)
  - … change the environment
  - …be sustainable
Examples – in theory

- Mass media programs for elderly people
  - Message: physical activity is normal, common, desirable also in high age; increases QoL; is fun
  - Increase offerings for physical activity
  - One example: strength and balance training

- Environment
  - Make public space accessible/usable/safe
  - Barrier-free buildings

- Education
  - Training of students
Strategies / measures (I)

Website & Booklet with offerings for physical activity for older people

Teaching of exercise instructors

Presentations

Use of the local mass media (print & radio)
Strategies / measures (II)

Awareness day

Schritt halten Journal

Otago-Programme

Booklet how to use public transport
Considerations about the evaluation (I)

- **Ethical considerations**
  - Paternalistic approach? – we approached the community

- **Effects / Impact**
  - Pilot study – only process evaluation planned
  - Outcome evaluation difficult:
    - e.g. a population 65+ not large enough to detect a reduction in femoral fractures within short time periods (power calculation)
  - Some of the effects may be seen not before several years (e.g. teaching of medical students concerning the prescription of sedatives)
  - Telephone interview (contact from two health insurances – controls from another medium-size town)
    - Response rate only 8%
    - No differences in awareness, fall rate, physical activity
  - Naïve expectations?
Considerations about the evaluation (II)

- Website (German / English)
  - Own strategies / interventions
  - Results, experiences
  - Further ideas
  - Materials
  
as a result of the process evaluation

- Methods
  - Otago exercise programme
    - Questionnaire completed by PT
    - Focus group with PT
Implementation research and impact factors

- publications included in Cochrane Reviews

![Graph showing impact factor for McClure et al. and Gillespie et al.]

- McClure et al., N=6 publications
- Gillespie et al., N=76 publications
The osteoporotic fracture prevention programme in rural areas (OFRA) - ‘Trittsicher durchs Leben’ (running)

Objective
- to enhance safe mobility of community-dwellers living in rural areas.

Programme
1. To motivate older people to participate in a Trittsicher-mobility and falls prevention course
2. To motivate for a bone density measurement
3. To offer a consultation about safety around the house and farm
Cooperation

- Rural health insurance (SVLFG), volunteer organisation of women (LandFrauenverband), the German Gymnastics Association (DTB) and the Robert-Bosch-Hospital

Target groups

- People with a fracture history
- Women aged 75-<80 years

Regions

- 47 districts in 5 federal states

Cluster-randomised implementation study

Begin: 10/2015

- Within 2 years, more than 10,000 people will be directly addressed by a prevention manager or by telephone
Implementation of Trittsicher-courses

- LandFrauen organise the courses in the countryside
  - Gym, fire station, pub, …
  - Exercise instructors from the local sport clubs (DTB) or PT
  - Materials (training booklet, weight-cuffs) delivered by the tele-centres
  - 6x90 min.

- Strategy (Legislative – new prevention law in Germany)
  - Courses are offered as setting approach (free) or will be (partly) reimbursed
Considerations about the evaluation

Effects / Impact (of the RCT)

- Outcome evaluation
  - Primary outcome: fractures (health claims data)
  - Good idea? (unclear: rate of interested people, participation rate (exercise, DXA), rate of osteoporosis in farmers, rate of drug treatment)
    - What’s about a pilot study?
- Process evaluation (Secondary outcome)
  - participation in exercise courses
  - DXA measurement
- Evaluation of structures
  - Education of 700 Trittsicher exercise instructors and 100 prevention managers in 2015
  - 200 Trittsicher-courses listed within the first 4 months
'Real world' examples (IV)

- Implementation of the Otago exercise programme (planned application)

- Background
  - In 2016 a call is expected (German Innovationsfonds)
  - Expected outcome: implementation of programmes in our medical health system
  - Funding: 300 million €/a
  - Only a few projects will be funded (highly competitive)
  - The implementation has to be evaluated (effectiveness)
Considerations about the evaluation

- Planned cooperation with 3 health insurance companies
  - Objective: widescaled implementation of the Otago exercise programme

- Outcome evaluation (Effects / Impact)
  - e.g. fractures
  - Appropriate selection of recipients is crucial
    - Screening procedure with routine data not sufficient
    - Second selection procedure necessary e.g. by GPs
  - Control group
    - Randomisation on an individual level?
    - Cluster-randomisation?

- Limitations in the evaluation of implementation studies
Lessons learned / conclusions

- Implementation trials/activities need a declared intention and a strong engagement of (health) political organizations.
  - Many partners are needed – they look on you as the scientific specialist – use it to influence the study design

- Implementation studies are complex procedures and their evaluation is not straightforward. Outcome evaluation is still important
  - But changes in outcome may need decades or may be difficult to measure
  - The evaluation of processes (reach, adoption, …) and structures is therefore of high value

- Publishing in high-ranked journals may be sometimes difficult, but remember: influencing and improving the 'real world' is also rewarding
Implementing Innovation into Policy and Practice

Trittsicher durchs Leben

Sie möchten auch in Zukunft Ihre Mobilität erhalten und möglichst lange in Ihrem Zuhause bleiben? Sie möchten bis ins hohe Alter Dinge tun, die das Leben lebenswert machen: mit den Enkelkindern spazieren gehen, dem Garten bestücken oder auf dem Hof mitarbeiten?

Trittsicher durchs Leben unterstützt Sie dabei, möglichst lange aktiv zu bleiben. Mitmachen können alle älteren Menschen, die im ländlichen Raum leben.

Machen Sie mit! Wir zeigen Ihnen, wie's geht:

- Erhalt der Mobilität, Förderung der körperlichen Fitness und Verhinderung von Stürzen
- Verbesserung der Knochengesundheit

Bologna, 24.02.2016