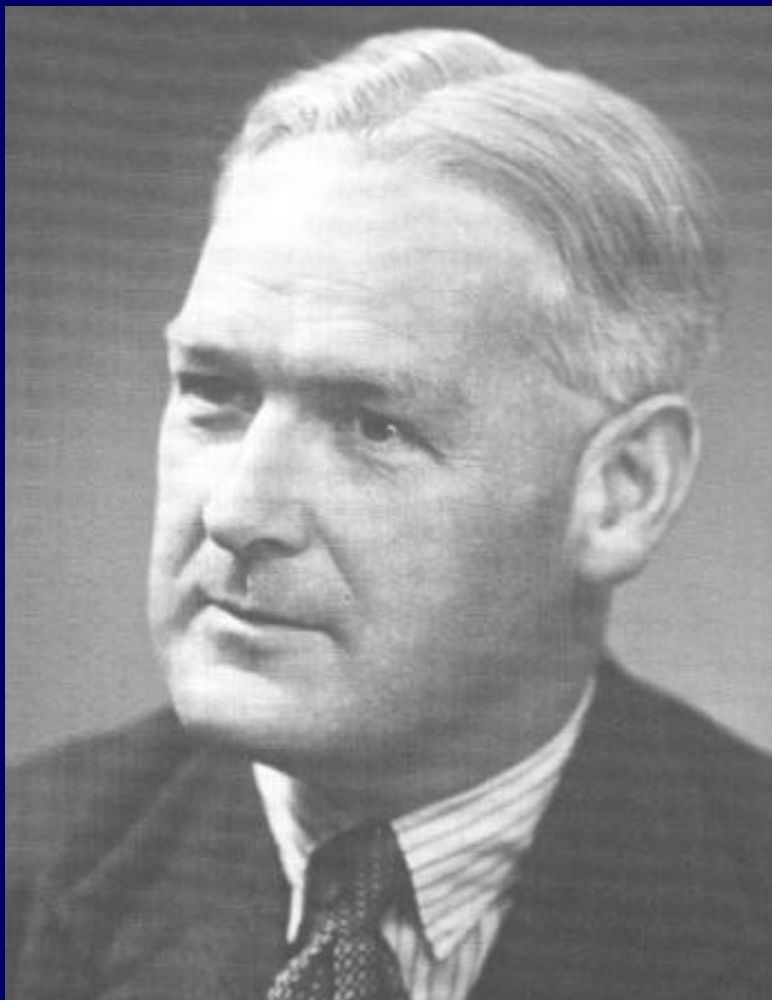


Designing and Evaluating Wellbeing Interventions for Older People

Using the MRC Framework/Guidance
to design complex interventions to
prevent falls amongst older people with
visual impairment

Chris Todd

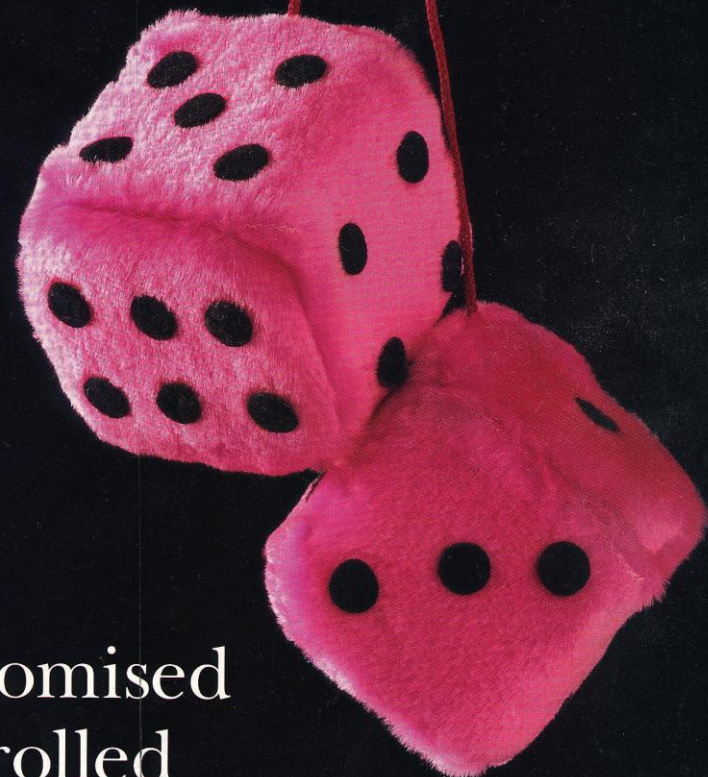
Professor of Primary Care & Community Health
Director of Research



Austin Bradford-Hill

BMJ

No 7167 31 October 1998



The
randomised
controlled
trial at 50

October 1998

MRC Framework/Guidance



A FRAMEWORK FOR DEVELOPMENT AND EVALUATION OF RCTs FOR COMPLEX INTERVENTIONS TO IMPROVE HEALTH

This document is a discussion document drafted by members of the MRC Health Services and Public Health Research Board. It is intended to provide a framework for individuals considering the evaluation of a complex intervention. It does not set out a set of required steps in carrying out trials in this area.

April 2000



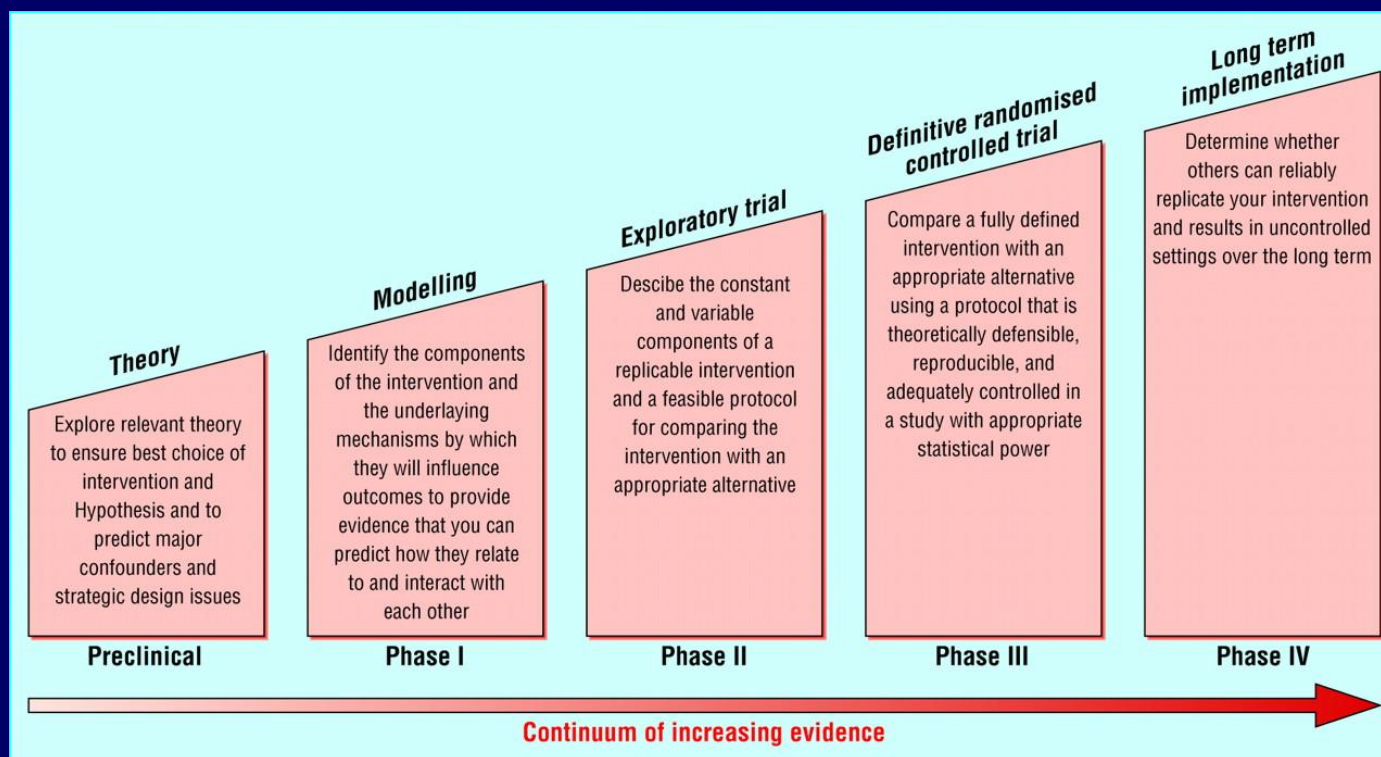
Developing and evaluating complex interventions: new guidance

Prepared on behalf of the Medical Research Council by:

Peter Craig, MRC Population Health Sciences Research Network
Paul Dieppe, Nuffield Department of Orthopaedic Surgery, University of Oxford
Sally Macintyre, MRC Social and Public Health Sciences Unit
Susan Michie, Centre for Outcomes Research and Effectiveness, University College London
Irwin Nazareth, MRC General Practice Research Framework
Mark Petticrew, Department of Public Health and Policy, London School of Hygiene and Tropical Medicine

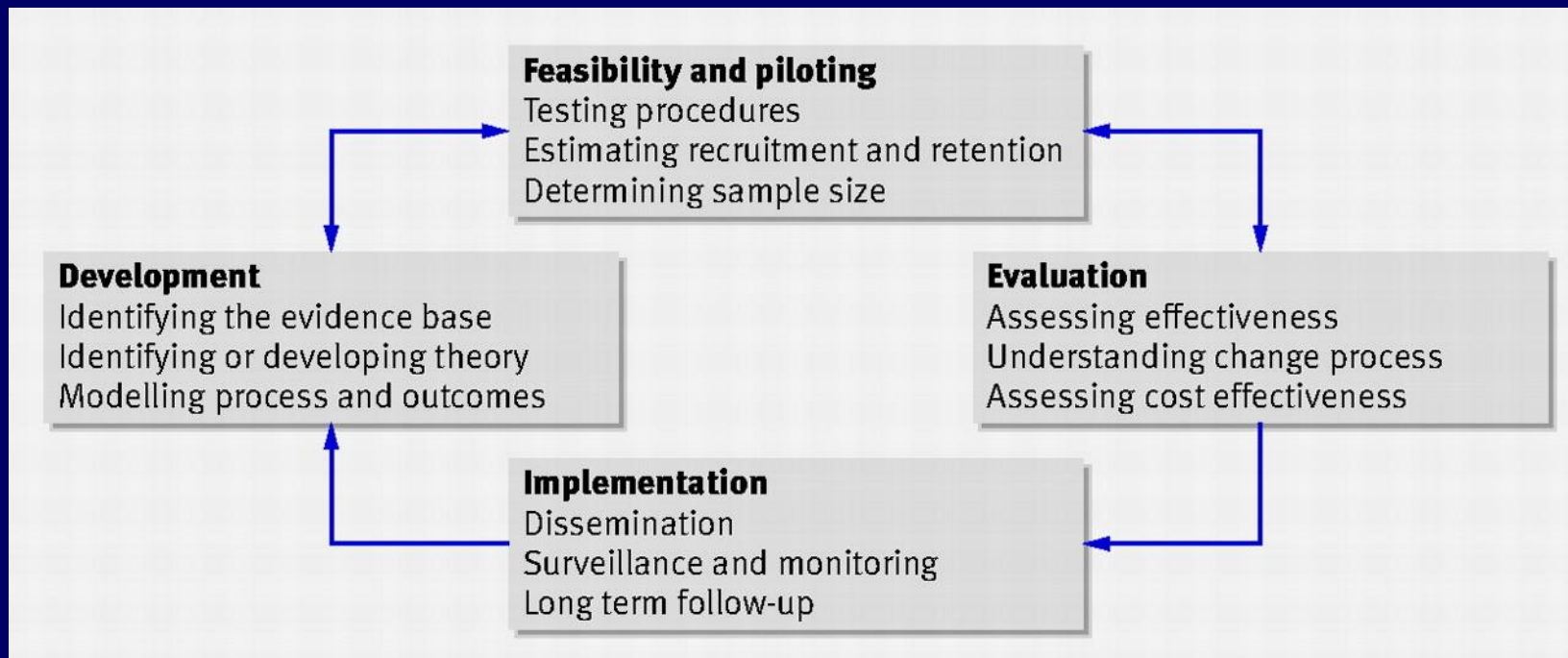
www.mrc.ac.uk/complexinterventionsguidance

MRC framework for complex interventions (2000)



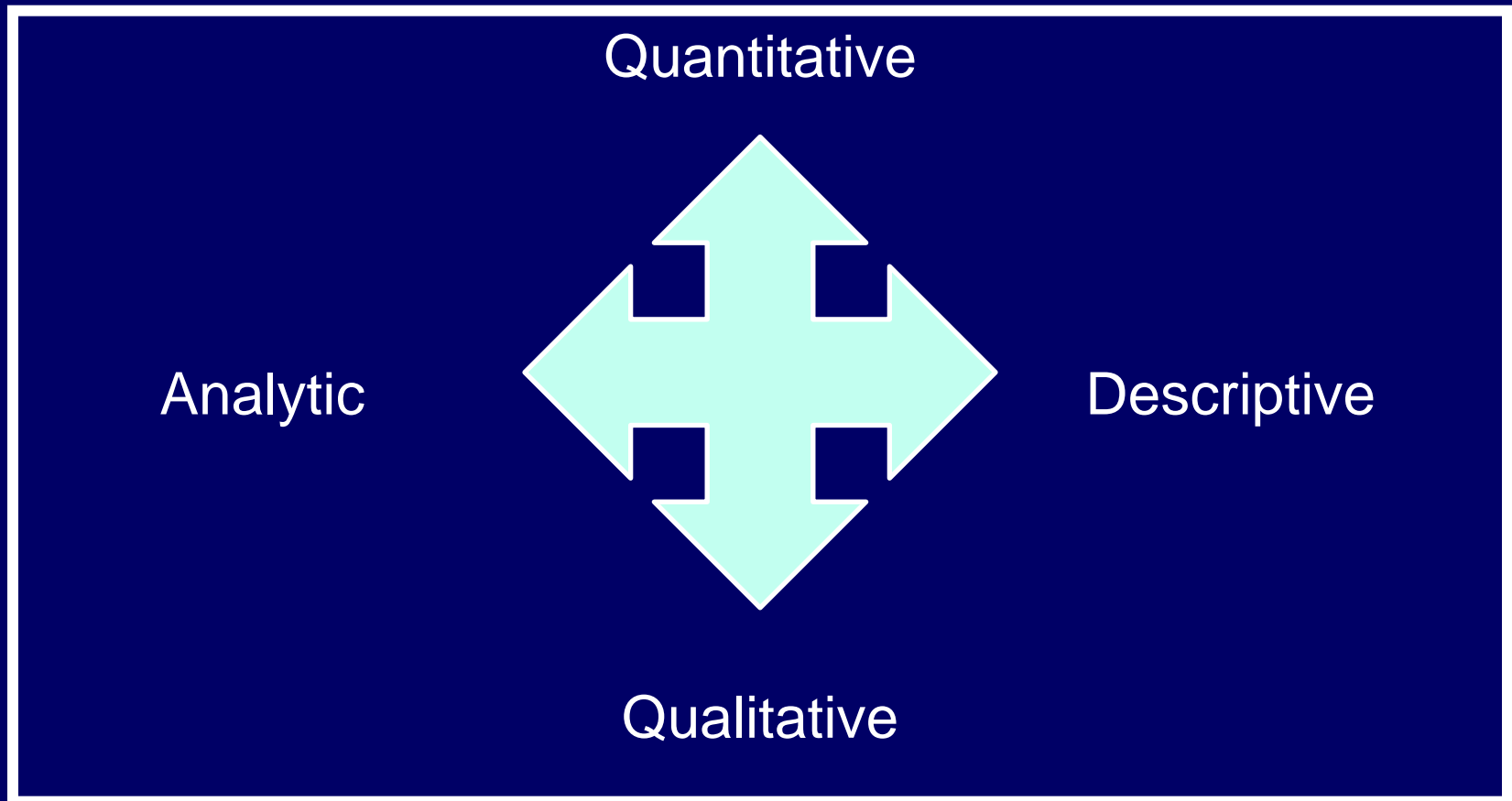
Campbell, M. et al. BMJ 2000;321:694-696

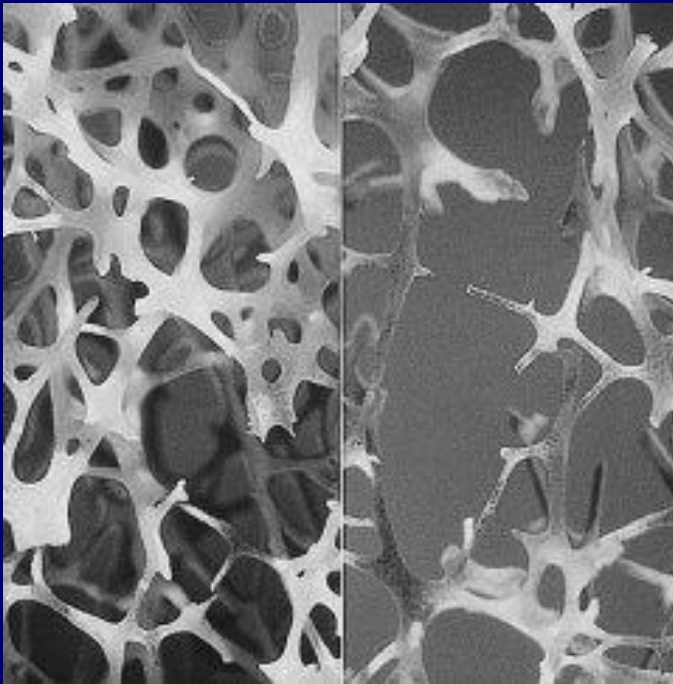
MRC Guidance for complex interventions (2008)



Craig P et al. BMJ 2008;337:bmj.a1655

Integrating quantitative & qualitative methods





Masud, Morris *Age & Ageing* 2001; 30-S4 3-7
Rubenstein. *Age & Ageing*; 2006; 35-S2; ii37-41

30-40% community
dwelling 65+ fall in a year

- 40-60% no injury
- 30-50% minor injury
- 5-6% major injury (excluding
fracture)
- 5% fractures
- 1% hip fractures

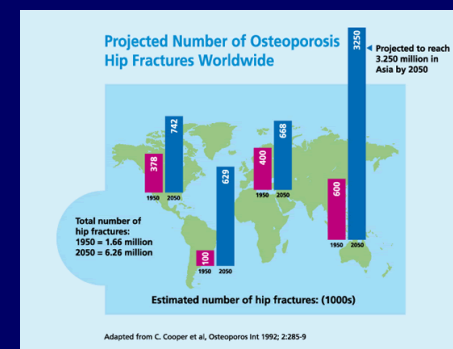
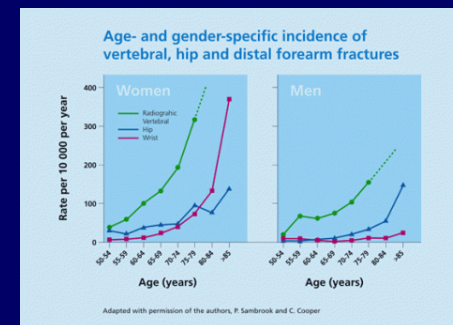
Falls most serious frequent
home accident

50% hospital admissions
for accidental injury due to
fall

History of falls a major
predictor future fall

- Consequences

- Injury
- Peripheral fractures
- Hip fractures
 - Common
 - Expensive to treat
 - Expensive for patients and families
 - » Money, morbidity, mortality and suffering
 - » 20% die within 90 days
 - » 50% survivors do not regain mobility
- Psychological and social consequences
 - Disability
 - Admission to long term care
 - Loss of independence
 - Falling most common fear of older people
 - More common than fear of crime or financial fear
 - Leads to activity restriction, medication use



Risk factors for falls (17 studies)

Risk factor	RR or OR	Range
Muscle weakness	4.9	1.9-10.3
Impaired balance	3.2	1.6-5.4
Gait deficit	3.0	1.7-4.8
Visual deficit	2.8	1.1-7.4
Limited mobility	2.5	1.0-5.3
Cognitive impairment	2.4	2.0-4.7
Impaired ADL	2.0	1.0-3.1
Postural hypotension	1.9	1.0-3.4

Interventions for preventing falls in older people living in the community (Review)

**Gillespie LD, Robertson MC, Gillespie WJ, Lamb SE, Gates S,
Cumming RG, Rowe BH**



**THE COCHRANE
COLLABORATION®**

2009

Interventions: Cochrane review 2009

- Exercise targets strength, balance, flexibility, endurance
 - programmes with 2 or more components reduce falls & fallers
- Supervised group exercise, Tai Chi, & individual prescribed at home can be effective
- Multifactorial assessment and referral works under certain circumstances
 - complex interventions causal mechanisms need clarification
- Appropriate medication review and withdrawal can reduce falls
- Environment
 - Home safety only effective for high risk- professionally administered
 - VIP
- Surgery in appropriate clinical populations can reduce falls
 - Cataract surgery, pacemakers (carotid sinus hypersensitivity)
 - Vitamin D does not reduce falls (except in low baseline) (?)

Rate of falls (Rate Ratios)

Group exercise: 0.78 [0.71, 0.86]

Individual exercise 0.66 [0.53, 0.82]

Group exercise: tai chi 0.63 [0.52, 0.78]

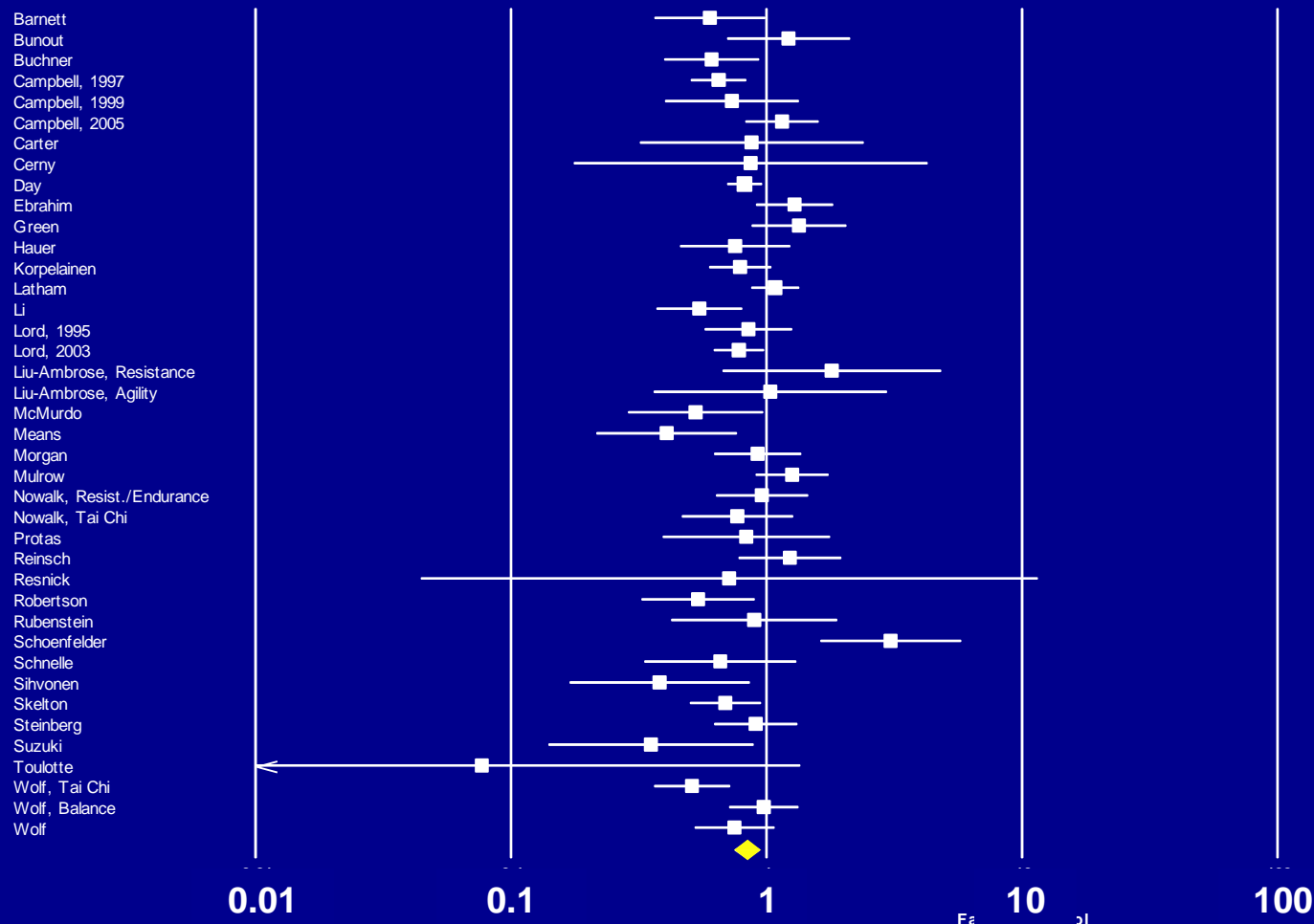
Group exercise: gait, balance or functional training 0.73 [0.54, 0.98]

Group exercise: strength/ resistance training 0.56 [0.19, 1.65]

Exercise effect RR=0.83, 95% CI=0.75-0.93, 17% reduction

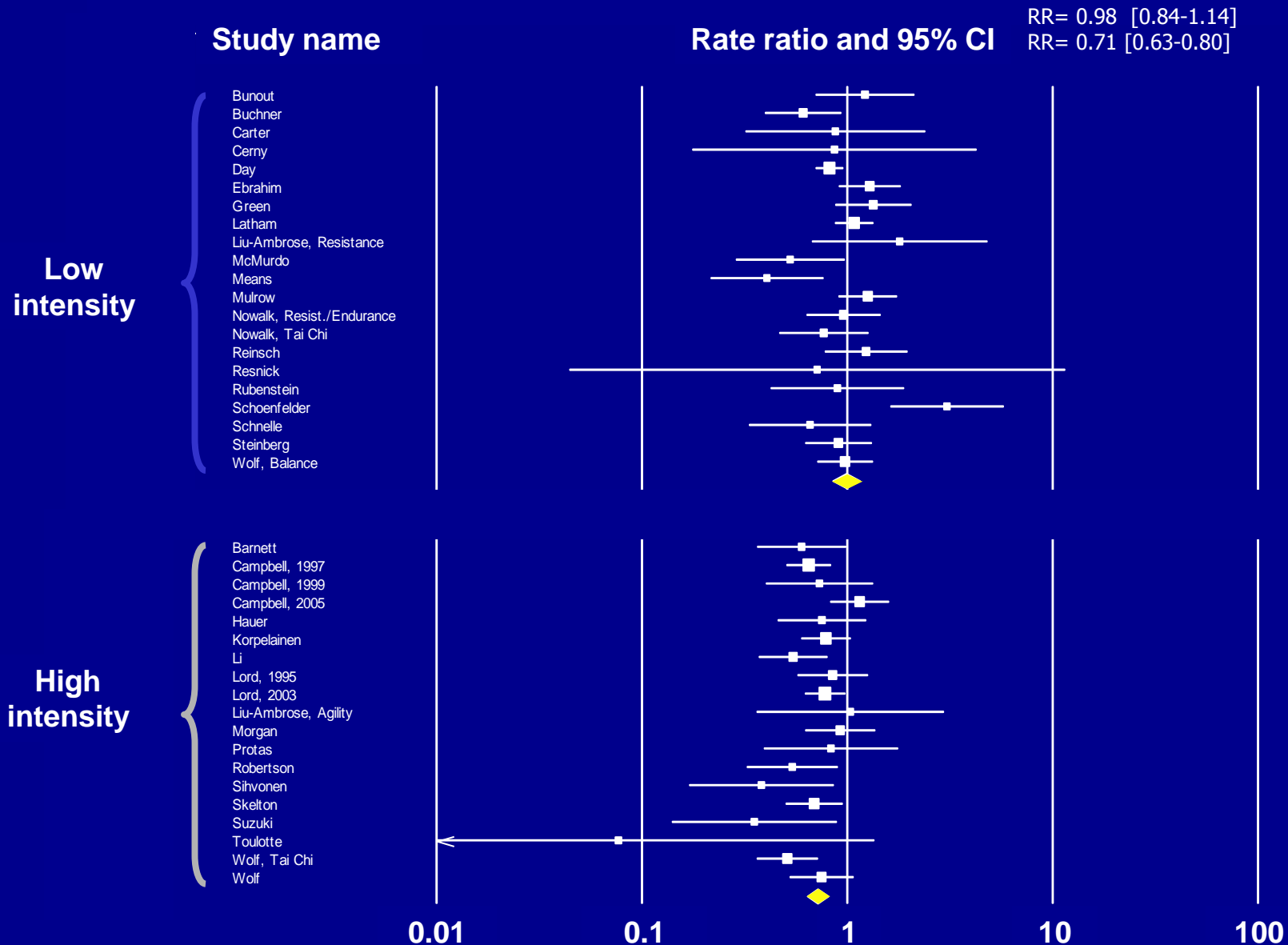
Study name

Rate ratio and 95% CI

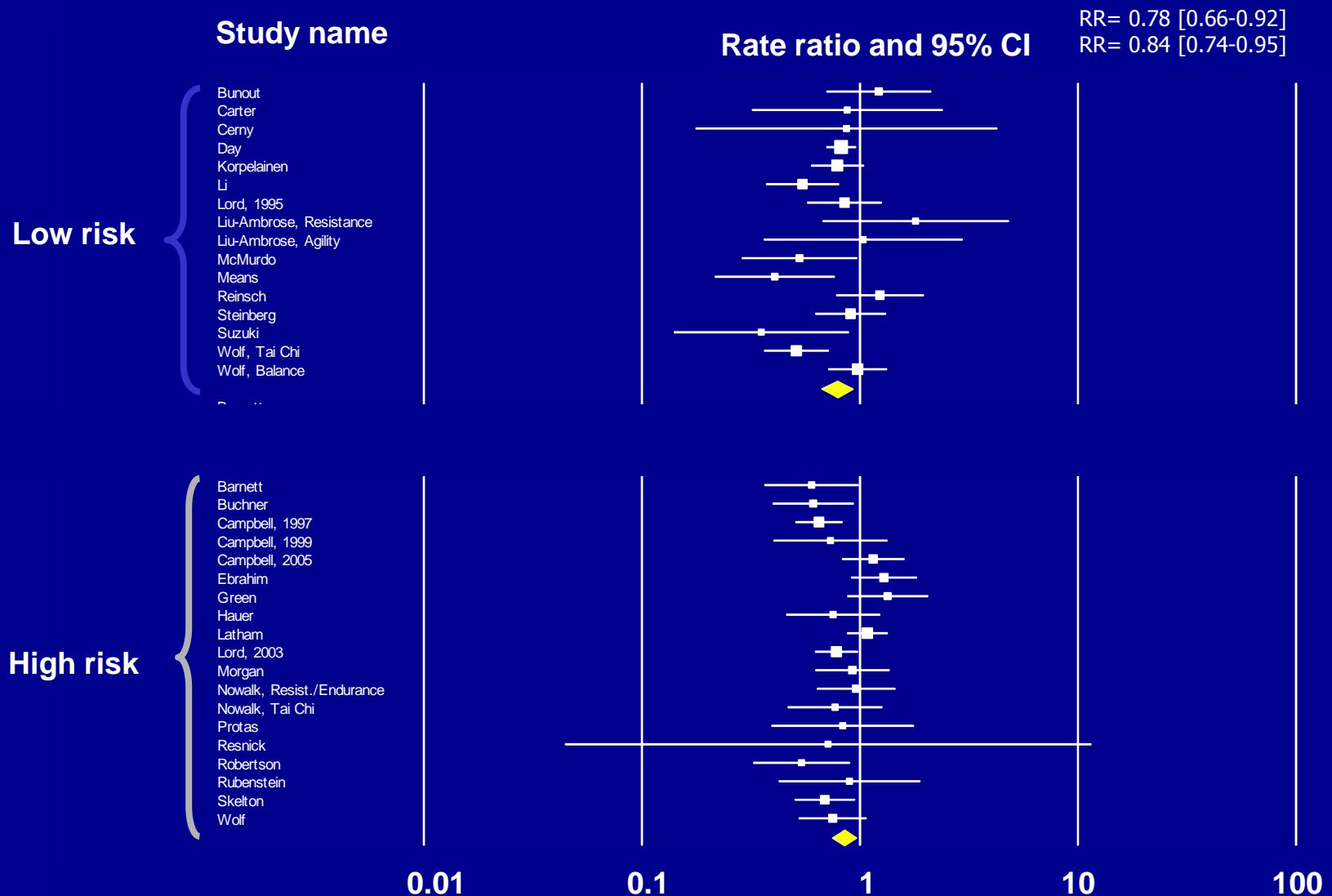


37 studies
40 comparisons
7111 subjects

Balance training intensity



Risk status



Algorithm for exercise prescription

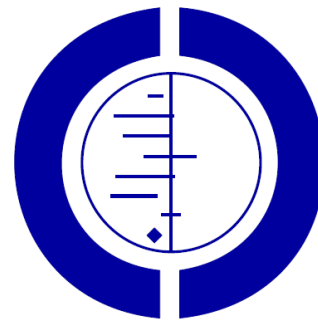
POPULATION	PROGRAM
Population Low Risk 60-80 Years	Tai Chi type exercises in groups
Population at Increased Risk 70-80 Years	Group balance and strength training
Population at Increased Risk 80 + Years	Otago exercise program

Sherrington, Whitney, Close, Herbert, Cumming, Lord . Exercise for preventing falls: meta-analysis ProFaNE WP2 Australia Falls Conference Brisbane 2006

Falls and the environment

Population-based interventions for the prevention of fall-related injuries in older people (Review)

McClure R, Turner C, Peel N, Spinks A, Eakin E, Hughes K



THE COCHRANE
COLLABORATION®

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2006, Issue 3

<http://www.thecochranelibrary.com>

Main results

Out of 23 identified studies, five met the criteria for inclusion. There were no randomised controlled trials. Significant decreases or downward trends in fall-related injuries were reported in all five of the included studies with the relative reduction in fall-related injuries ranging from 6 to 33%.

Randomised controlled trials of environmental assessment and modification on falls in community samples. (Ballinger, Todd, Whitehead, 2007)

AUTHORS	PARTICIPANTS	INTERVENTION	FINDINGS	COMMENTS
Cumming <i>et al</i> (1999)	530 people aged 65+	Home assessment and supervision Occupational therapist	Not effective for participants who hadn't experienced a previous fall Reduced falls in people who had fallen previously	Reduction in falls outside the home
Day <i>et al</i> (2002)	1090 people, mean age 76.1 (SD 5.5)	Home assessment, advice and provision of materials and labour Trained assessor	Not effective in reducing falls	Significant reduction in home hazards
Nikolaus and Bach (2003)	360 people, mean age 81.5 (SD 6.4)	Home assessment, advice and training in use of devices Occupational therapists and physiotherapists	Effective in reducing falls	Particularly effective in those with a history of multiple falls
Pardessus <i>et al</i> (2002)	60 people aged 65+	Home assessment, advice, information about living safely with hazards Occupational therapist	Not effective in reducing falls	Underpowered for falls as outcome measure
Stevens <i>et al</i> (2001)	1737 people aged 70+	Home assessment, education, free installation of safety devices Trained nurse assessor	Not effective in reducing falls	Significant reduction in home hazards

Visual impairment in UK

- 1/5 to 1/10 people >75 years
- 1/2 to 1/4 people >85 years
 - depending on threshold
- Many older people with visual impairments
 - fail to access services
 - report concern about falling

NZVIP Trial

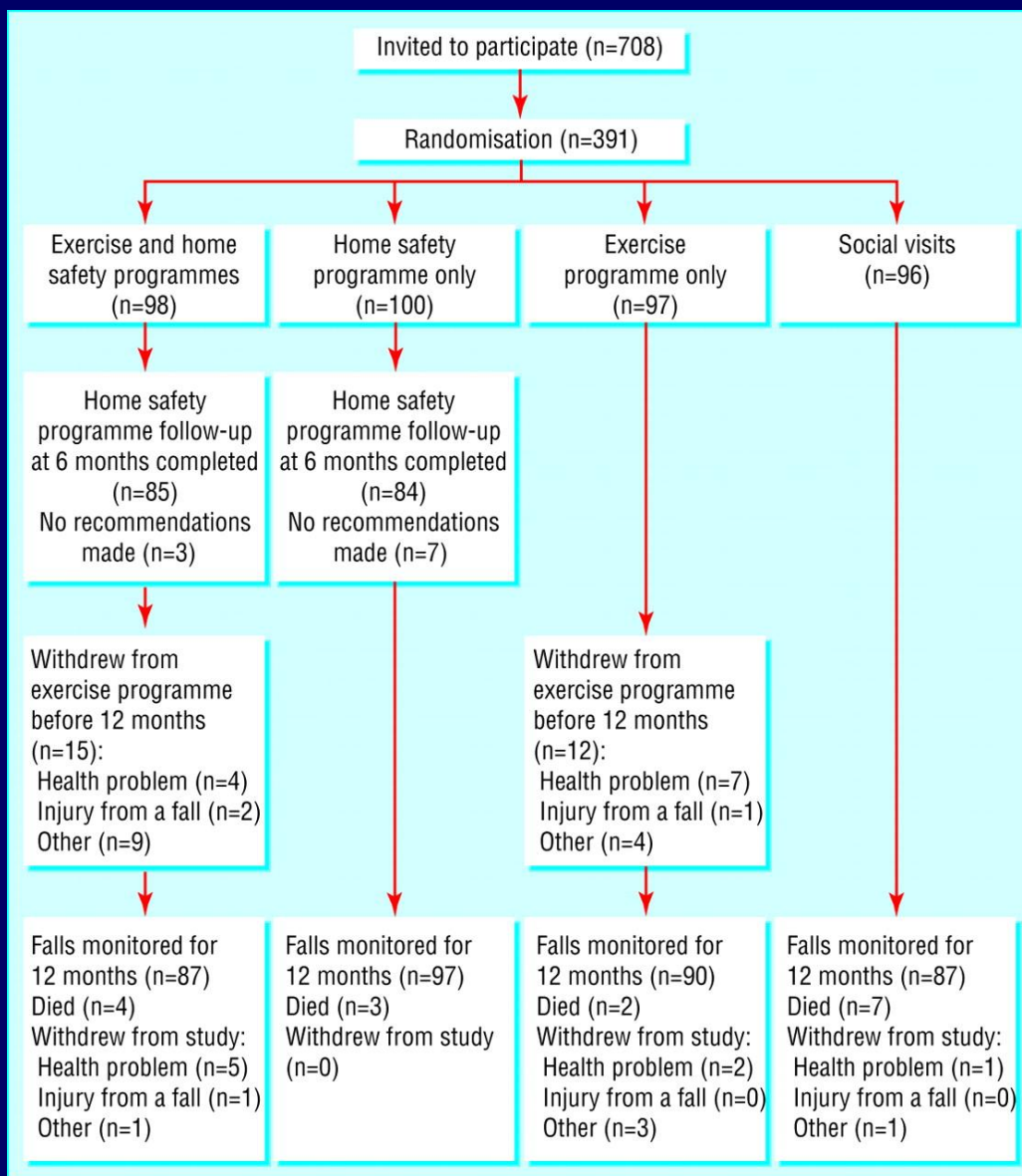
Randomised controlled trial of prevention of falls in people aged ≥ 75 with severe visual impairment: the VIP trial

A John Campbell, M Clare Robertson, Steven J La Grow, Ngaire M Kerse, Gordon F Sanderson, Robert J Jacobs, Dianne M Sharp, Leigh A Hale

Campbell A J et al. BMJ 2005;331:817

BMJ

Flow of participants through the NZVIP trial



Campbell A J et al. BMJ 2005;331:817

Results

NZVIP trial

Incidence rate ratio (95%
CI)

Effect on falls

Home safety programme:

All receiving home safety programme (n=198) v all not receiving home safety programme (n=193)	0.59 (0.42 to 0.83)
---	---------------------

Home safety programme only group (n=100) v social visits group (n=96)	0.39 (0.24 to 0.62)
---	---------------------

Exercise programme:

All receiving exercise programme (n=195) v all not receiving exercise programme (n=196)	1.15 (0.82 to 1.61)
---	---------------------

Exercise programme only group (n=97) v social visits group (n=96)	0.79 (0.48 to 1.28)
---	---------------------

Campbell A J et al. BMJ 2005;331:817

BMJ

Results

NZVIP trial

	Separate intervention groups				Combined intervention groups			
	Home safety + exercise programmes (n=98)	Home safety programme alone (n=100)	Exercise programme alone (n=97)	Social visits alone (n=96)	Home safety programme (n=198)	No home safety programme (n=193)	Exercise programme (n=195)	No exercise programme (n=196)
No of falls	108	64	120	151	172	271	228	215
Falls per person year	1.17	0.65	1.30	1.65	0.90	1.47	1.23	1.13

Campbell A J et al. BMJ 2005;331:817

Results

NZVIP trial

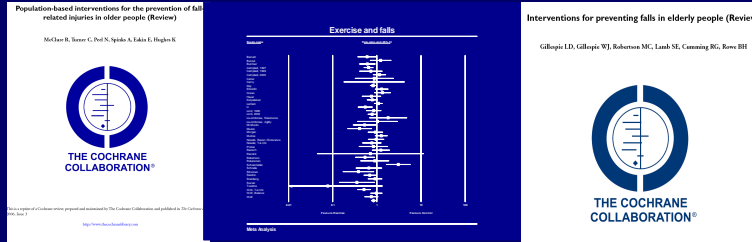
Table 4 Incidence of falls by level of adherence to home exercise sessions*

	<1 session/week (n=53)	1 to <2 sessions/week (n=35)	2 to <3 sessions/week (n=70)	≥3 sessions/week (n=37)
No of falls	98	57	55	18
Falls per person year	2.16	1.69	0.80	0.49
Incidence rate ratio (95% CI)	1.00	0.79 (0.42 to 1.50)	0.37 (0.23 to 0.60)	0.23 (0.12 to 0.45)

Campbell A J et al. BMJ 2005;331:817

NZ-VIP trial

- Compared to those not receiving the programme
 - fewer falls amongst home safety programme
 - but not exercise programme
 - within exercise programme, stricter adherence associated with fewer falls
 - adherence to exercise programme not as good as in the general older population
- **“One size fits all” approach does not work**
 - People with visual impairment have different needs to those with good sight
 - Adherence to exercise regimen and issues to do with interaction between interventions, appear to be important
 - Home safety programme seemed less effective when the person was also receiving the exercise programme



- Prevention programmes are *efficacious*
- Refusal/non-adherence 50% - 90% thus prevention may not be *effective*
- Training needs to be challenging, progressive and done regularly.



Qualitative studies of people's attitudes to fall prevention

- C Todd, M Horne, D Skelton, S Whitehead
 - University of Manchester, UK
- L Yardley, F Bishop,
 - University of Southampton, UK
- N Beyer,
 - Copenhagen University Hospital, Denmark
- K Hauer,
 - Robert-Bosch-Krankenhaus, Stuttgart & University of Heidelberg, Germany
- G Kempen, R Zijlstra
 - Maastricht University, The Netherlands
- C Piot-Ziegler, T Cuttelod,
 - University of Lausanne, Switzerland
- Y Ben-Shlomo, R Gilbert
 - University of Bristol

The studies

1. UK Qualitative interviews and focus groups
2. UK Quantitative surveys
3. EU Qualitative interviews and focus groups

Yardley L, Todd C et al

Older people's views of advice about falls prevention: A qualitative study. *Health Education Research*. 2006. 21(4); 508-517.

Attitudes and beliefs that predict older people's intention to undertake strength and balance training. *Journals of Gerontology Series B-Psychological Sciences & Social Sciences*. 2007; 62(2): 119-25,

Encouraging positive attitudes to falls prevention in later life. London: Help the Aged 2005

Older people's views of falls prevention interventions in Six European countries. *The Gerontologist*. 2006. 46(5) 650-660.

Recommendations for promoting the engagement of older people in activities to prevent falls. *Quality and Safety in Health Care*. 2007 16 230-234.

How likely are older people to take up different falls prevention activities? *Preventive Medicine* 2008 47 554-558

Socio-demographic factors predict the likelihood of not returning home after hospital admission following a fall *Journal of Public Health* 2010 32 117-24

Qualitative studies of older people's attitudes to fall prevention

- Surprising degree of convergence across Europe
- Older people generally rejected or denied any personal need for 'falling prevention'
- Appreciated immediate benefits of strength and balance training such as improved mobility, confidence, mood and independence. Multiple physical and psychosocial benefits of falls prevention programmes motivate participation (especially maintaining independence)
- Social approval and support important (outside as well as inside programme)
- Group-based programmes are ideal for some people but can pose problems for others
- Low perceived need for falls prevention may be a barrier – this may relate to reluctance to accept identity as 'at risk' (old, incompetent)

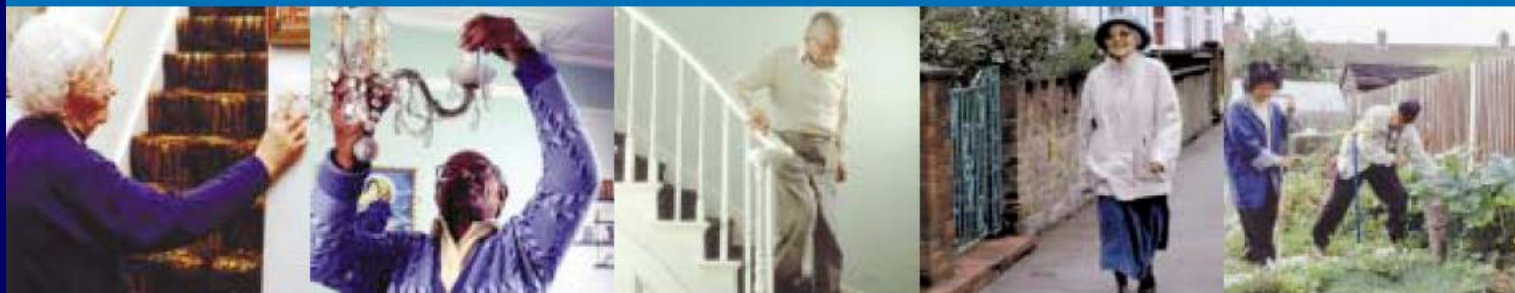
preventing falls... preventing falls... preventing falls... preventing falls... preventing falls...

Preventing *Falls*

Don't mention the f-word!



Advice to practitioners on communicating falls prevention messages to older people



Implications for practice

Do not present initially to older people in terms of falling prevention (since falling risk denied anyway)

Talk in terms of **A**ctivity

Emphasise/maximise immediate wider **B**enefits: looking and feeling good; remaining active and independent; taking part in an enjoyable and interesting **C**ommunal/social activity

Most effective approach is personal invitation from health professional explaining exactly what is involved, benefits.

Illness, evidence of increasing **D**isability provides good opportunity to suggest taking this up.

Exercise in terms of everyday activities

“F” word

Recommendations for promoting the engagement of older people in activities to prevent falls.

Quality and Safety in Health Care. 2007; 16: 230-234.

1. **Raise awareness in the general population that undertaking specific physical activities has the potential to improve balance and prevent falls**
2. **When offering or publicising interventions, promote benefits which fit with a positive self-identity**
3. **Utilise a variety of forms of social encouragement to engage older people in interventions**
4. **Ensure the intervention is designed to meet the needs, preferences and capabilities of the individual**
5. **Encourage self-management rather than dependence on professionals by giving older people an active role**
6. **Draw on validated methods for promoting and assessing the processes that maintain adherence, especially in the longer-term**

Intention to carry
out Strength &
Balance Training

.09

.87

Threat appraisal

Fear of falling (FES-I)

Perceived vulnerability
- risk of falling

Perceived severity -
consequences of falling

Perceived causes
of falling

Coping appraisal

Expected benefits of
SBT

Expected attitudes of
others

Expected ability to carry
out SBT

Identity right to do SBT

MRC Framework/Guidance



A FRAMEWORK FOR DEVELOPMENT AND EVALUATION OF RCTs FOR COMPLEX INTERVENTIONS TO IMPROVE HEALTH

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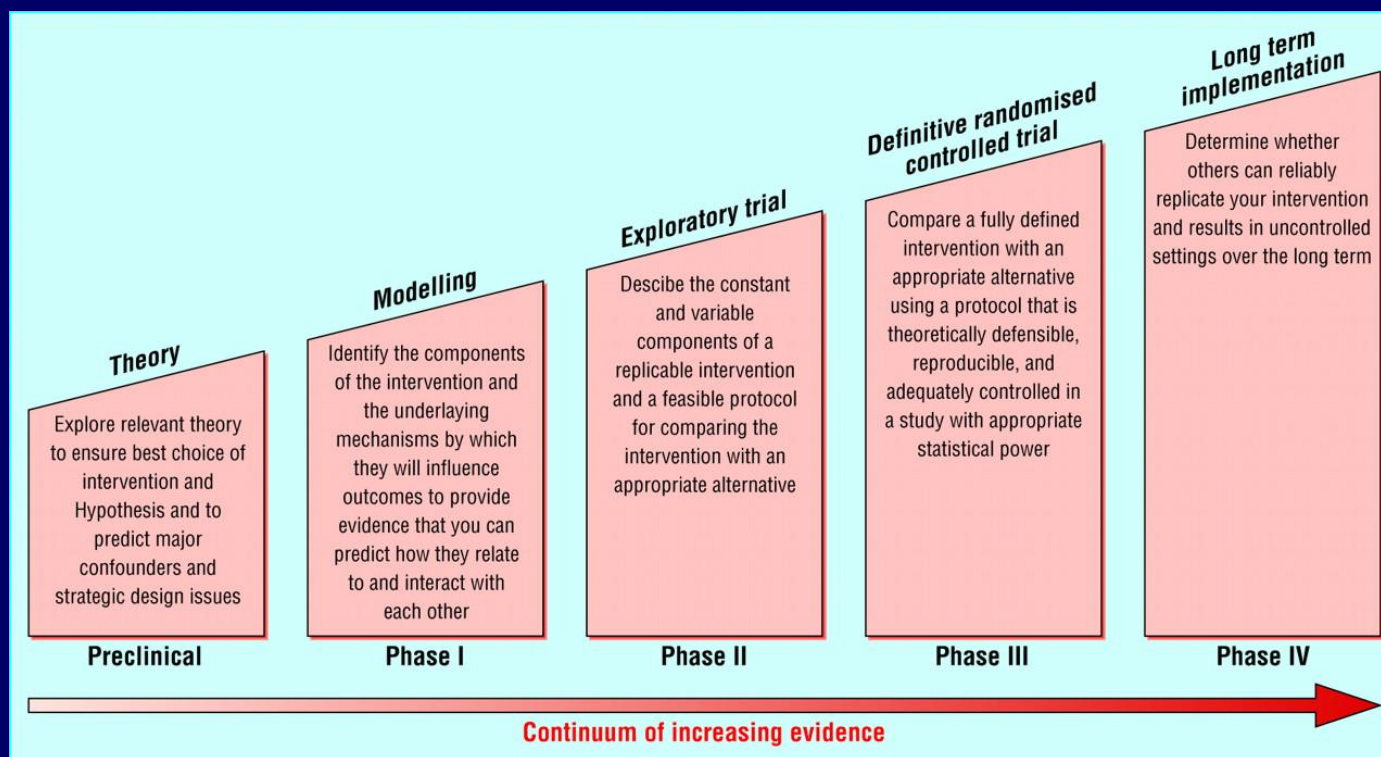
Developing and evaluating complex interventions: new guidance

Prepared on behalf of the Medical Research Council by:

Peter Craig, MRC Population Health Sciences Research Network
Paul Dieppe, Nuffield Department of Orthopaedic Surgery, University of Oxford
Sally Macintyre, MRC Social and Public Health Sciences Unit
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Irwin Nazareth, MRC General Practice Research Framework
Mark Petticrew, Department of Public Health and Policy, London School of Hygiene and Tropical Medicine

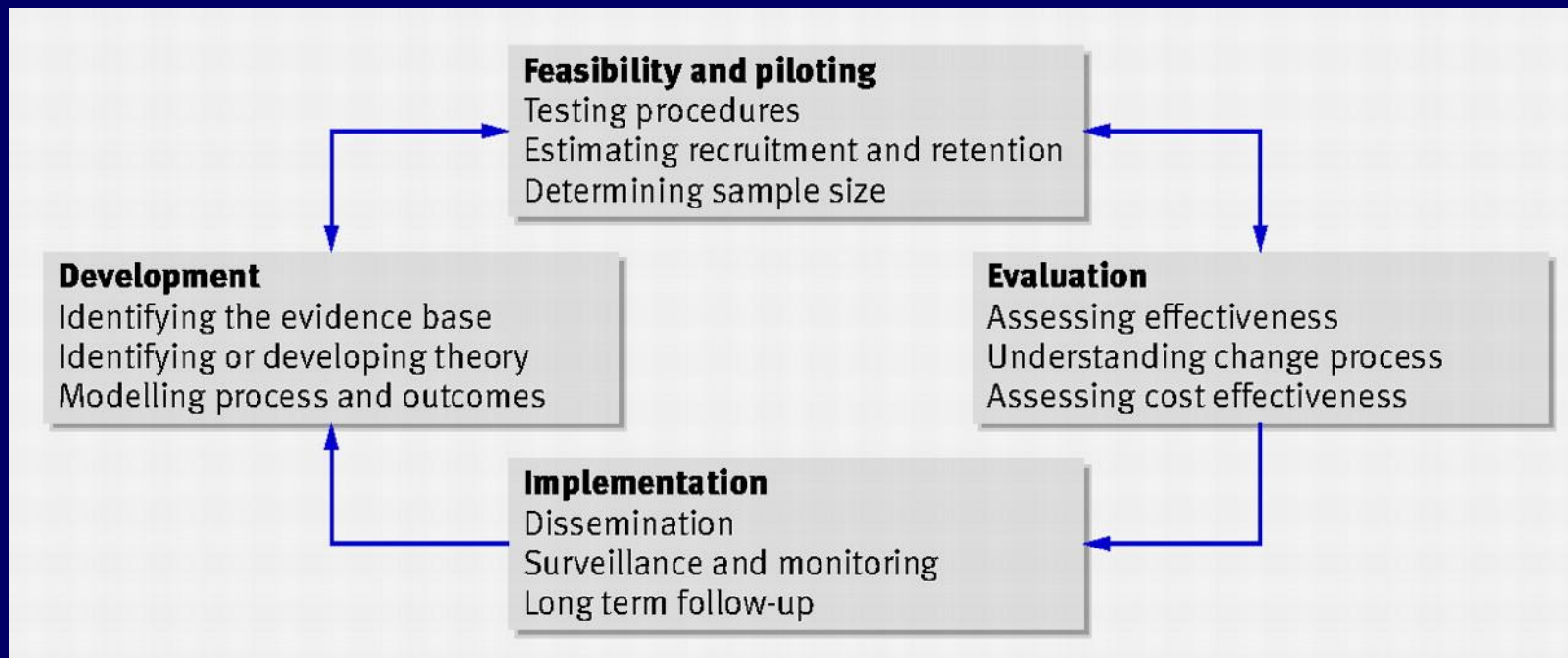
www.mrc.ac.uk/complexinterventionsguidance

MRC framework for complex interventions (2000)



Campbell, M. et al. BMJ 2000;321:694-696

MRC Guidance for complex interventions (2008)



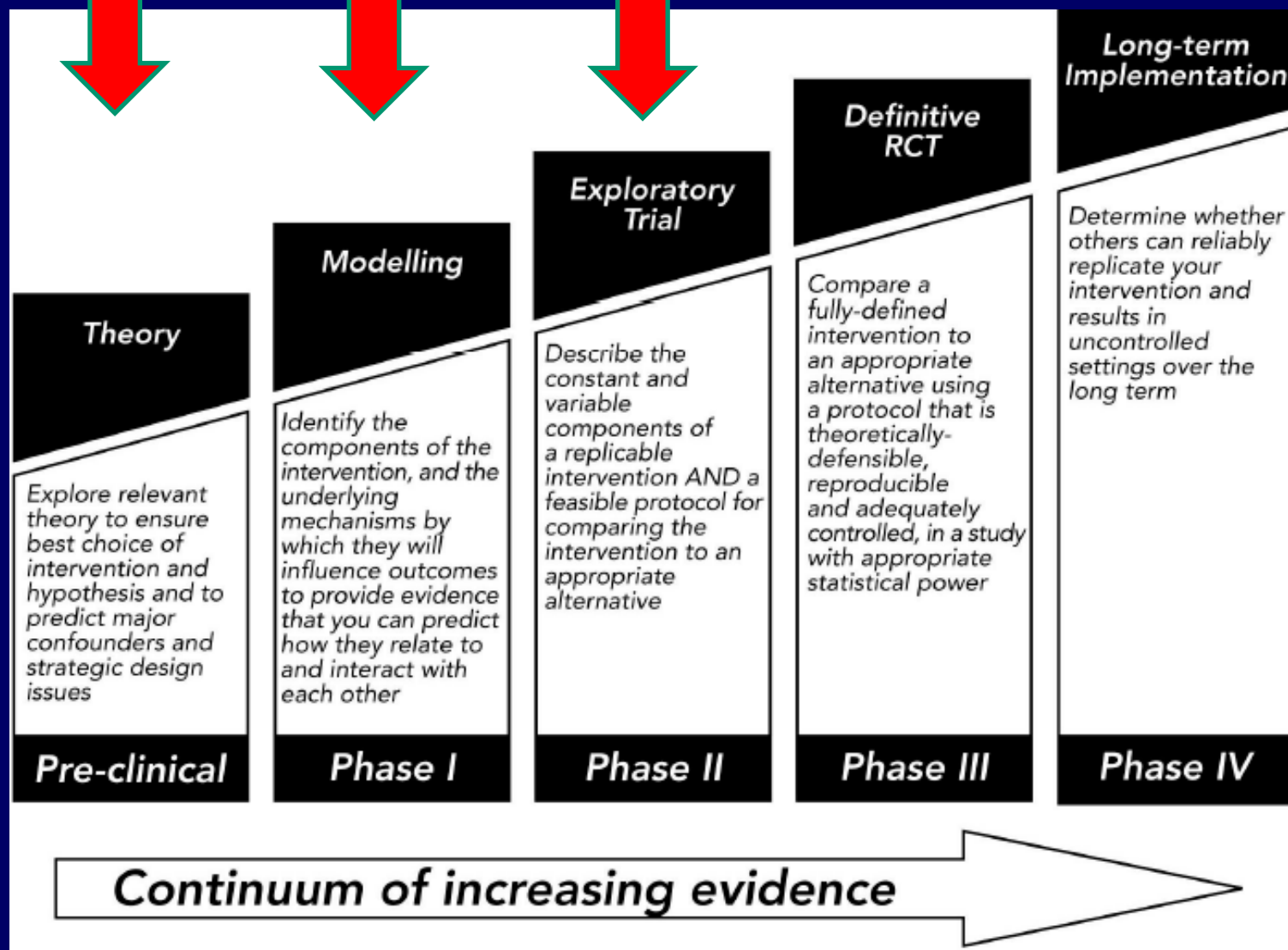
Craig P et al. BMJ 2008;337:bmj.a1655

VIP2UK

RfPB funded development and
pilot study of falls prevention
amongst older people with
visual impairments.

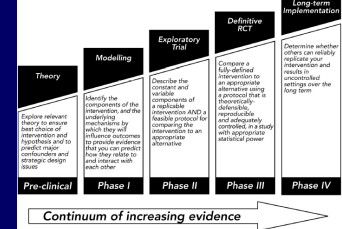
VIP2UK Team

- Heather Waterman
- Chris Todd
- Robert Harper
- Dawn Skelton
- Claire Ballinger
- David Henson
- Malcolm Campbell
- Caroline Brundle
- Penelope Stanford
- John Campbell
- Clare Robertson
- Heather Gage
- Mark Pilling
- Lisa McEvoy
- Sarah Buchanan

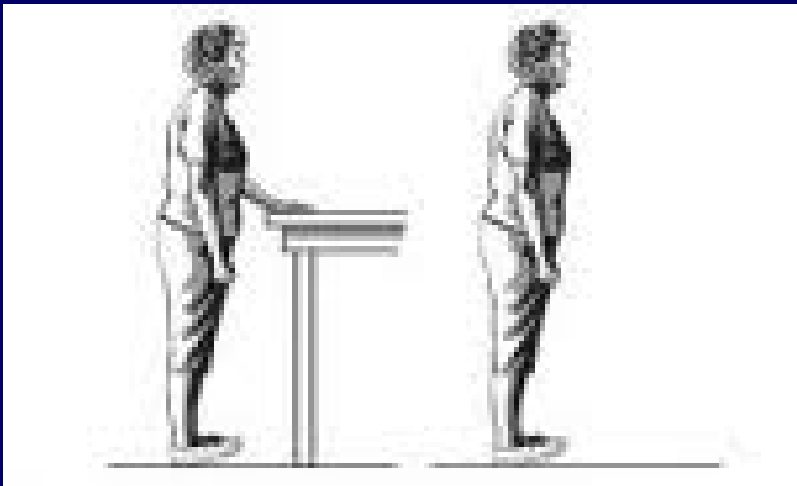


Theoretical & Phase I Modelling

- Reviews of literature
- Work on the intervention
- Qualitative work with people with visual impairment & health care professional to clarify the best way to design & present the interventions



Otago exercises



**Training needs to be challenging,
progressive, regular and aimed at strength and balance.**

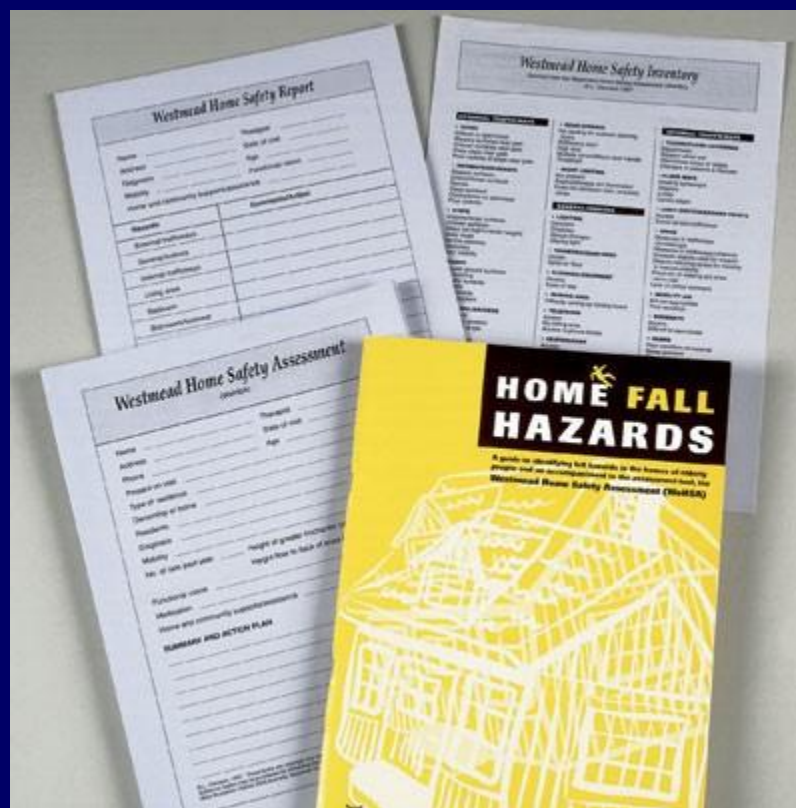


www.laterlifetraining.co.uk



Otago exercises

Westmead Home Safety Assessment



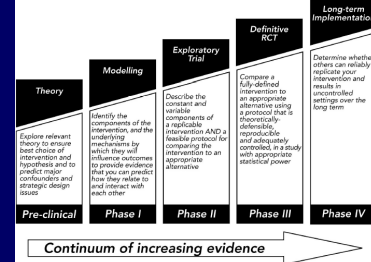
Environment modification

S Iwarsson Lund University



- Slippery walking surfaces
- Lack of handrails
- Hazards
- Visual pattern

Phase 2: Exploratory trial feasibility & acceptability



Recruit participants from
Eye Hospital
Baseline measurement &
randomisation

Occupational therapist
home
safety programme only

Occupational therapist
home
safety programme +
Otago Exercise Programme

Usual care
with social visits

Inclusion/exclusion criteria

Vision related inclusion criteria:

Binocular visual acuity less than 0.6 LogMAR (Snellen equivalent 6/24), stratified into

0.6-1.0 LogMAR (1.0 LogMar = Snellens 6/60),

>1.0 LogMAR and/or

Moderate visual field loss, defined as affecting more than 20% of the test location used in a binocular Estermann test, stratified into

missing 20-50% of the test locations

missing >50% of the test locations

Other inclusion criteria:

Aged 75 years & over

Independent community dwelling

Able to walk around their own residence

Cognitively able to participate in the programme

Able to understand the study requirements

Exclusion criteria

Receiving OT or physiotherapist intervention or home assessment & modification or exercise intervention eg. Falls Clinic

Cognitive impairment assessed by Abbreviated Mental Test