Focus on Care Research: Development and evaluation of complex interventions

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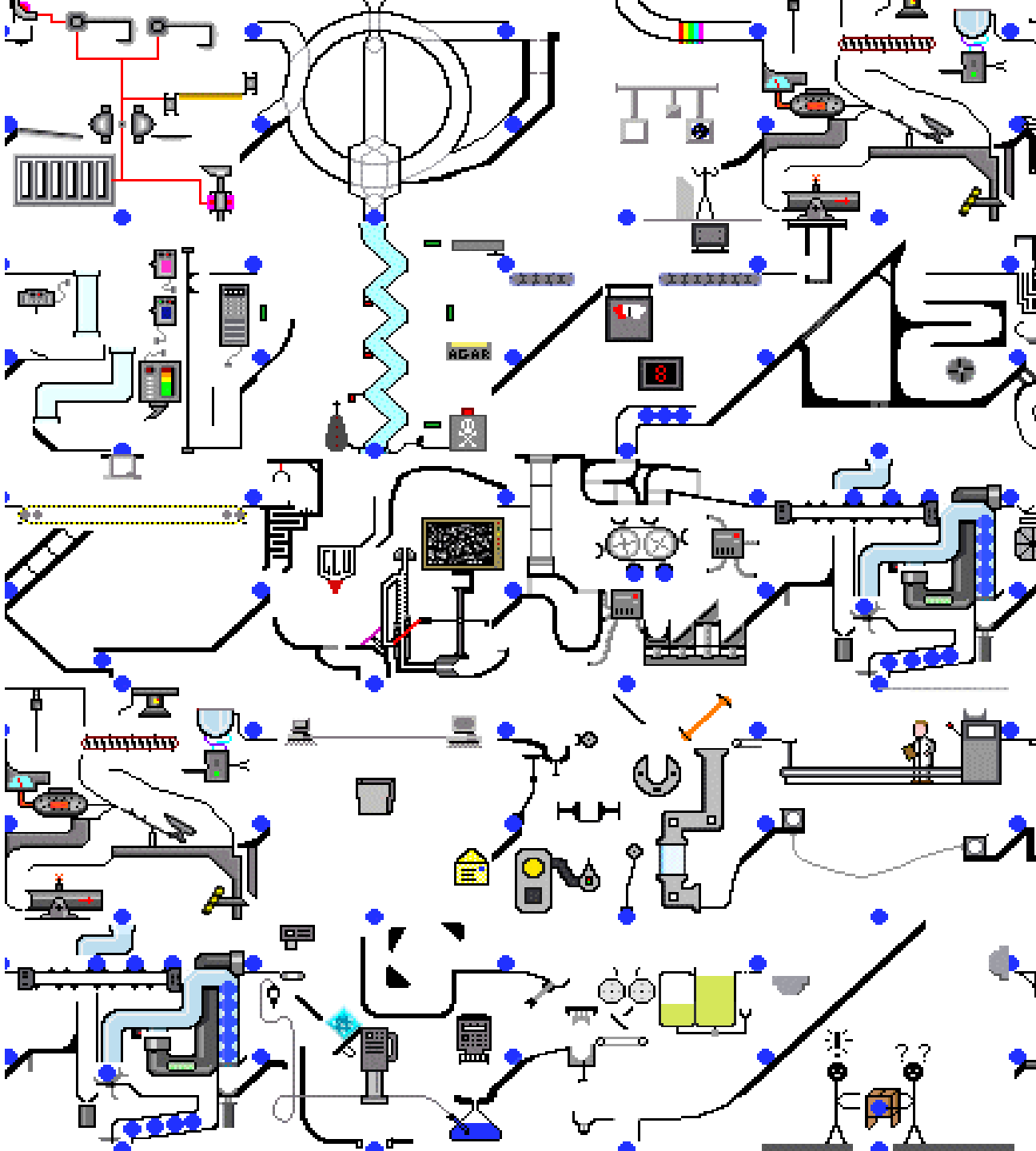


Complex interventions are …

- „built up from a number of components, which may act both independently and interdependently.“
- „more than the sum of their parts, and interventions need to be better theorised to reflect this.“ (Craig et al. 2008, BMJ; Hawe et al. 2004, BMJ)

Box 1. What makes an intervention complex?

- Number of interacting components within the experimental and control interventions.
- Number and difficulty of behaviours required by those delivering or receiving the intervention.
- Number of groups or organisational levels targeted by the intervention.
- Number and variability of outcomes.
- Degree of flexibility or tailoring of the intervention permitted.

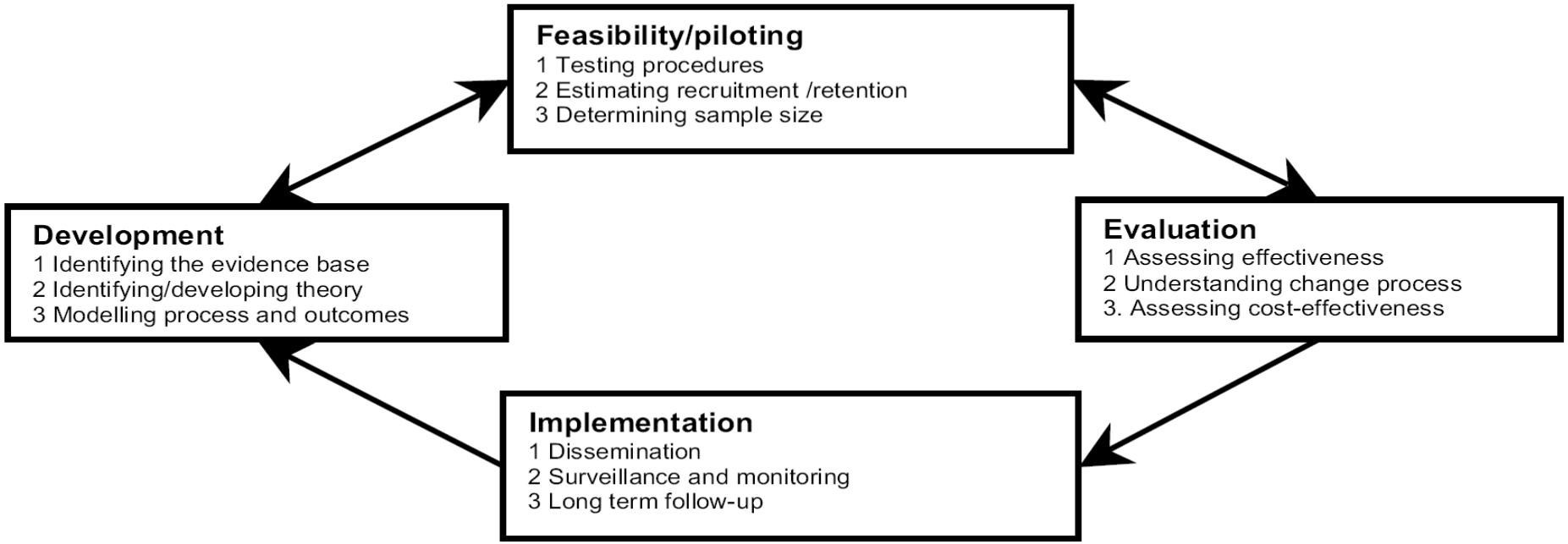
(Craig et al. 2012; IJNS)

The MRC framework

Developing and evaluating complex interventions:

new guidance

Figure 1 Key elements of the development and evaluation process

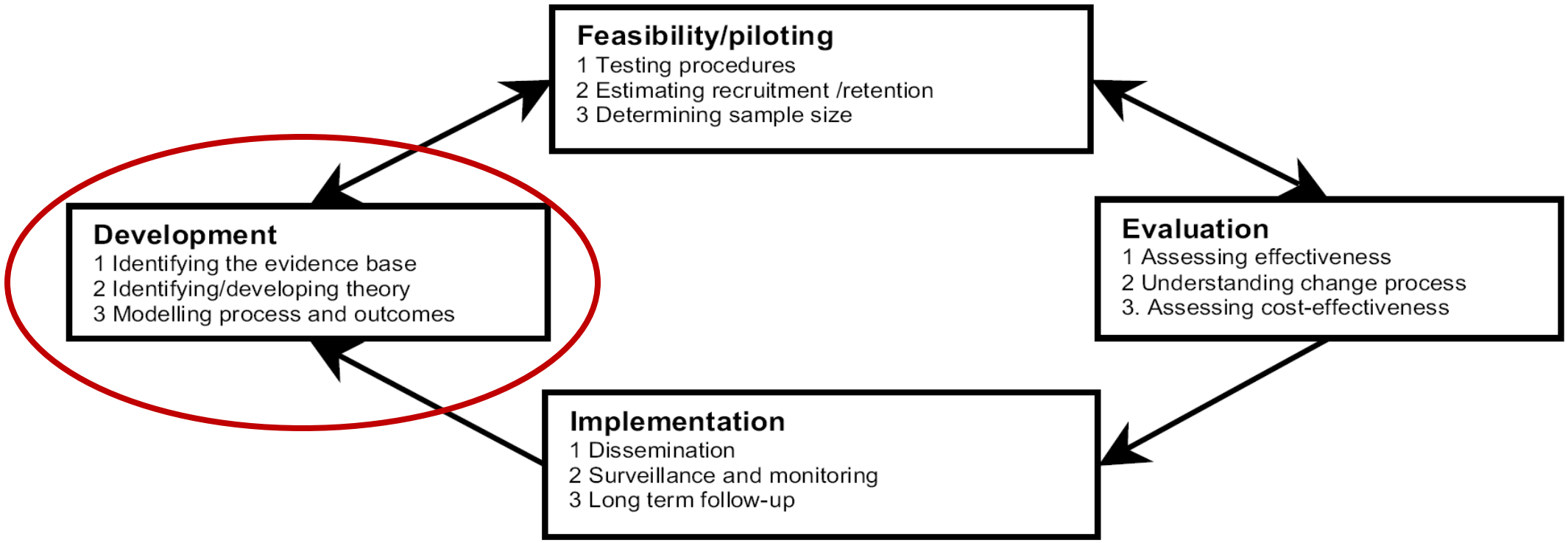


Worst case scenario

Introduction of the medical emergency team (MET) system: a cluster-randomised controlled trial

Introduction of such a system did not significantly reduce the incidence of our study outcomes. Possible explanations for our findings are that the MET system is an ineffective intervention; the MET is potentially effective but was inadequately implemented in our study; we studied the wrong outcomes; control hospitals were contaminated as a result of being in the study; the hospitals we studied were unrepresentative; or our study did not have adequate statistical power to detect important treatment effects.

Figure 1 Key elements of the development and evaluation process



MRC 2008

Key challenges to systematic reviews of complex interventions

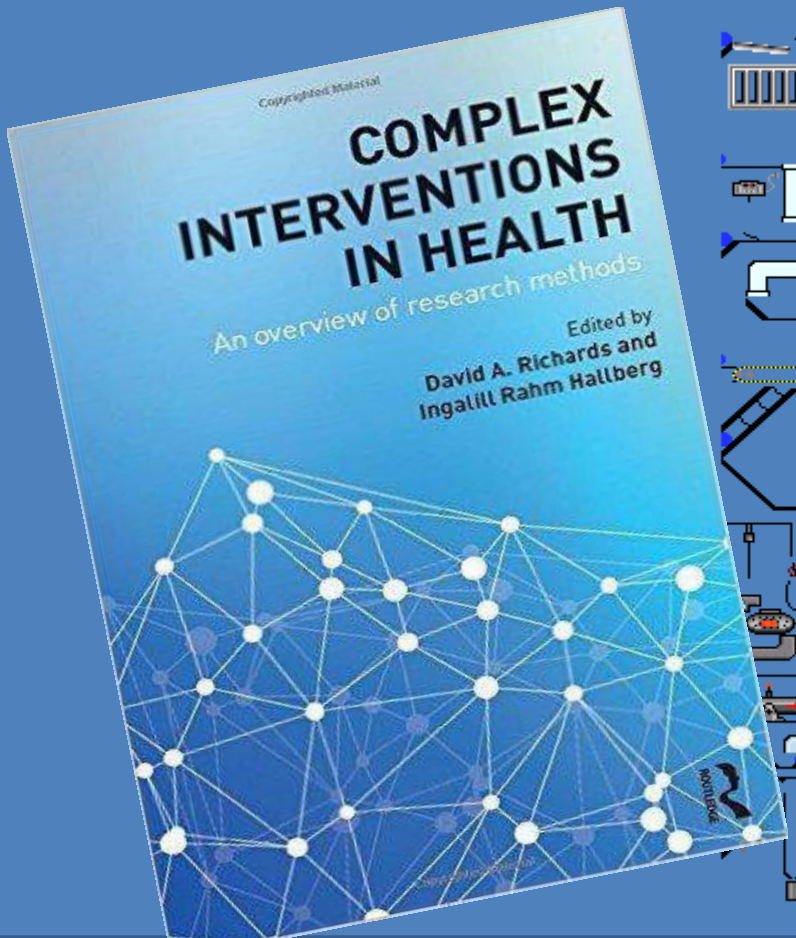
OPEN ACCESS Freely available online

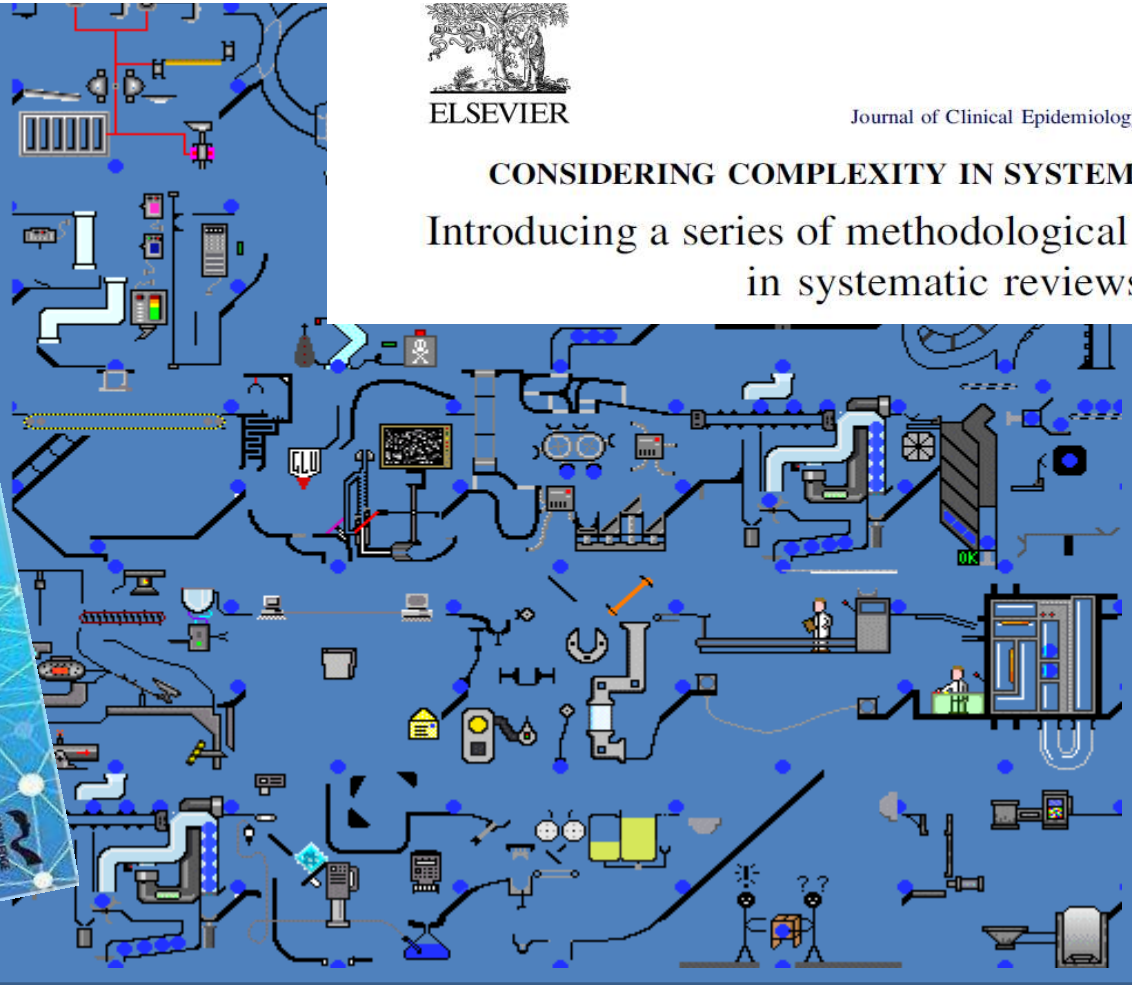
PLOS MEDICINE

The PLoS Medicine Debate

Can We Systematically Review Studies That Evaluate Complex Interventions?

Sasha Shepperd[1]*, Simon Lewin[2,3], Sharon Straus[4], Mike Clarke[5,6], Martin P. Eccles[7], Ray Fitzpatrick[1], Geoff Wong[8]*, Aziz Sheikh[9,10]*





ELSEVIER

Journal of Clinical Epidemiology 66 (2013) 1205–1208

Journal of Clinical Epidemiology

CONSIDERING COMPLEXITY IN SYSTEMATIC REVIEWS OF INTERVENTIONS

Introducing a series of methodological articles on considering complexity in systematic reviews of interventions

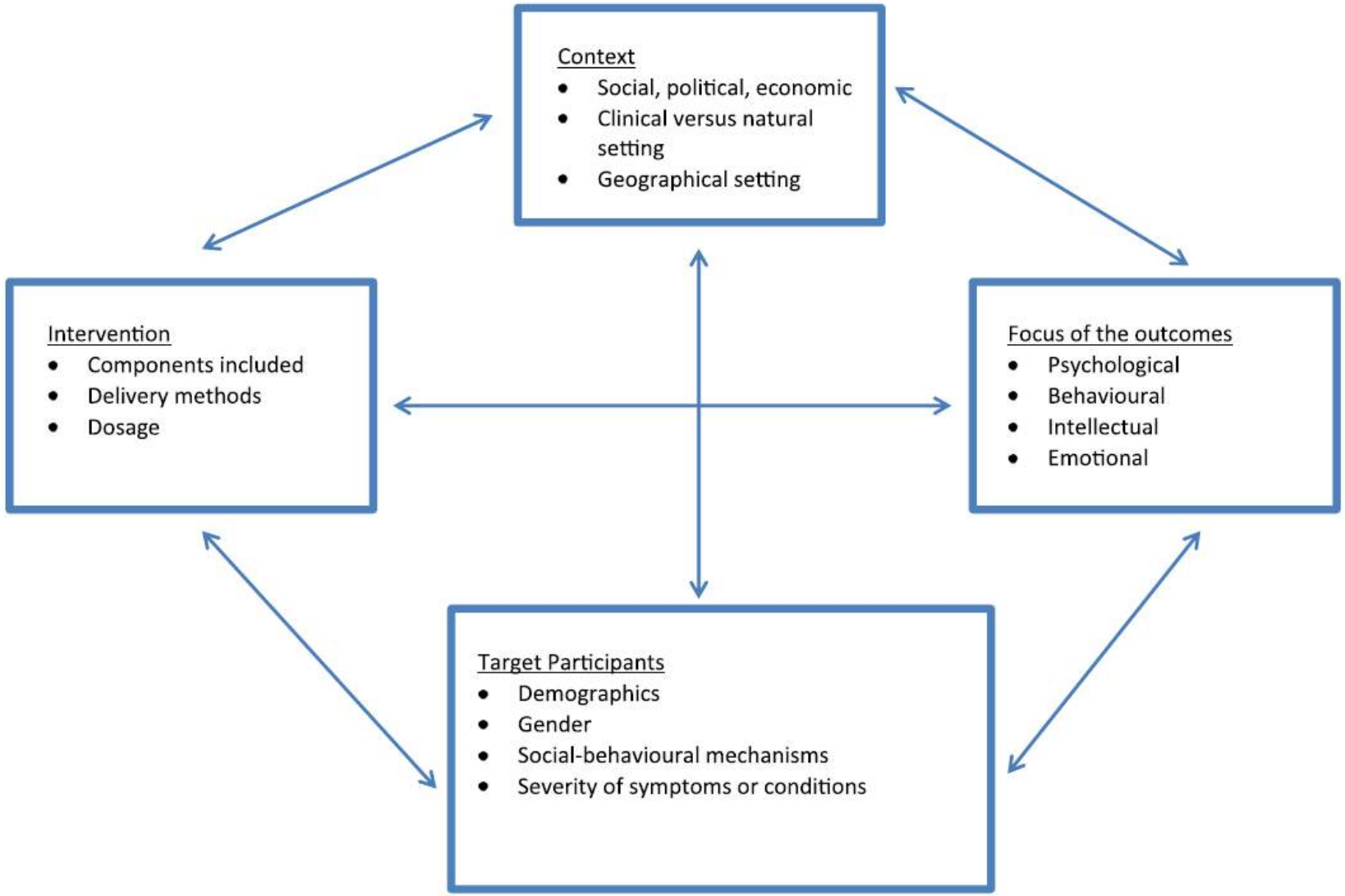


Fig. 1. Substantive features of a complex intervention that can lead to heterogeneity of results.

BMJ

RESEARCH

Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: methodological study

Simon Lewin, senior lecturer,[1,2] Claire Glenton, senior researcher,[3] Andrew D Oxman, senior researcher[3]

BMJ 2009;339:b3496

Box 1 Ways in which qualitative methods can be used alongside randomised controlled trials

Before a trial

- To explore issues related to the healthcare question of interest or context of the research
- To generate hypotheses for examination in the randomised controlled trial
- To develop and refine the intervention
- To develop or select appropriate outcome measures

During a trial

- To examine whether the intervention was delivered as intended, including describing the intervention as delivered
- To "unpack" processes of implementation and change
- To explore deliverers' and recipients' responses to the intervention

After a trial

- To explore reasons for the findings of the trial
- To explain variations in effectiveness within the sample
- To examine the appropriateness of the underlying theory
- To generate further questions or hypotheses

Pflege 2013; 26 (3): 207–214 DOI 10.1024/1012-5302/a000292

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Mette Spliid Ludvigsen[1] (Post-Doctoral Researcher, PhD, MScN, RN), Gabriele Meyer[2] (Professor Dr. phil.), Elisabeth Hall[3] (Professor Emerita, PhD, MSc N, RN), Liv Fegran[4] (Associate Professor, PhD, MScN, RN), Hanne Aagaard[1,3] (Assistant professor, PhD, MScN, RN), Lisbeth Uhrenfeldt[3,5] (Assistant professor, PhD, MScN, BA, RN)

Development of clinically meaningful complex interventions – The contribution of qualitative research

Domecq et al. BMC Health Services Research 2014, 14:89
http://www.biomedcentral.com/1472-6963/14/89

BMC Health Services Research

RESEARCH ARTICLE Open Access

Patient engagement in research: a systematic review

Juan Pablo Domecq[1,2,5], Gabriela Prutsky[1,2,5], Tarig Elraiyah[1,5], Zhen Wang[1,5,6], Mohammed Nabhan[1,5], Nathan Shippee[1,5,6], Juan Pablo Brito[1,4,5], Kasey Boehmer[1,5], Rim Hasan[1,5,8], Belal Firwana[1,5,8], Patricia Erwin[1,7], David Eton[1,5,6], Jeff Sloan[1,5,6], Victor Montori[1,2,4,5,6], Noor Asi[1,5], Abd Moain Abu Dabrh[1,5] and Mohammad Hassan Murad[1,3,5,6*]

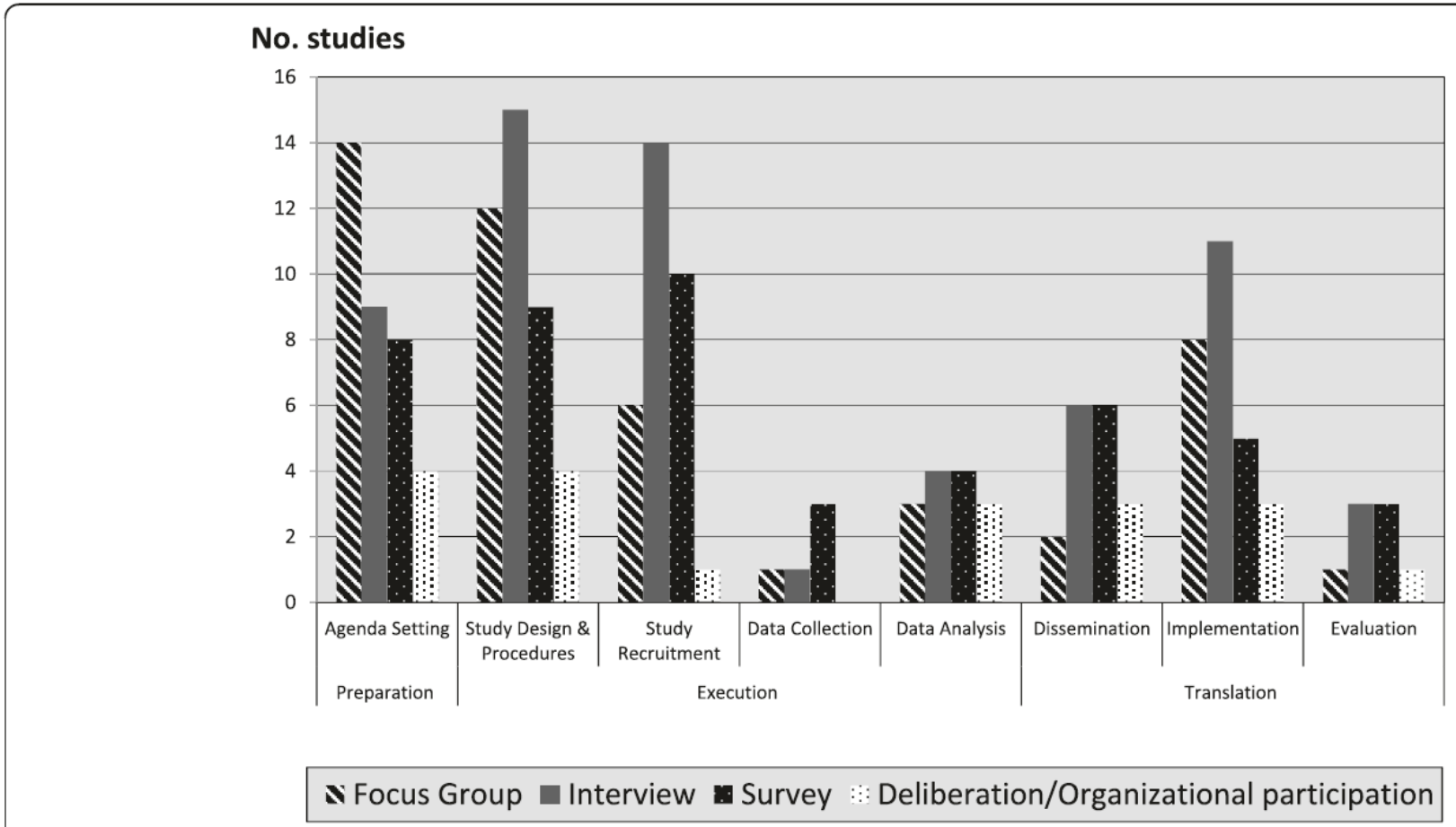
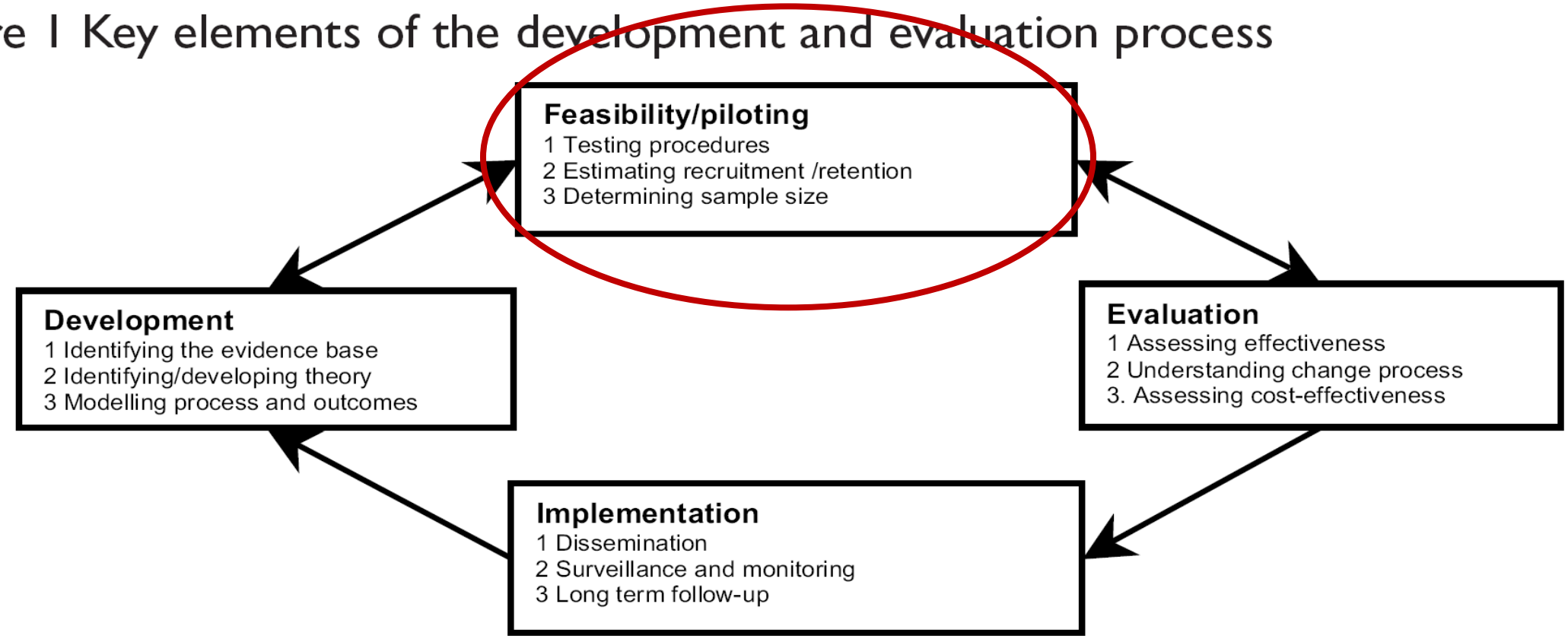
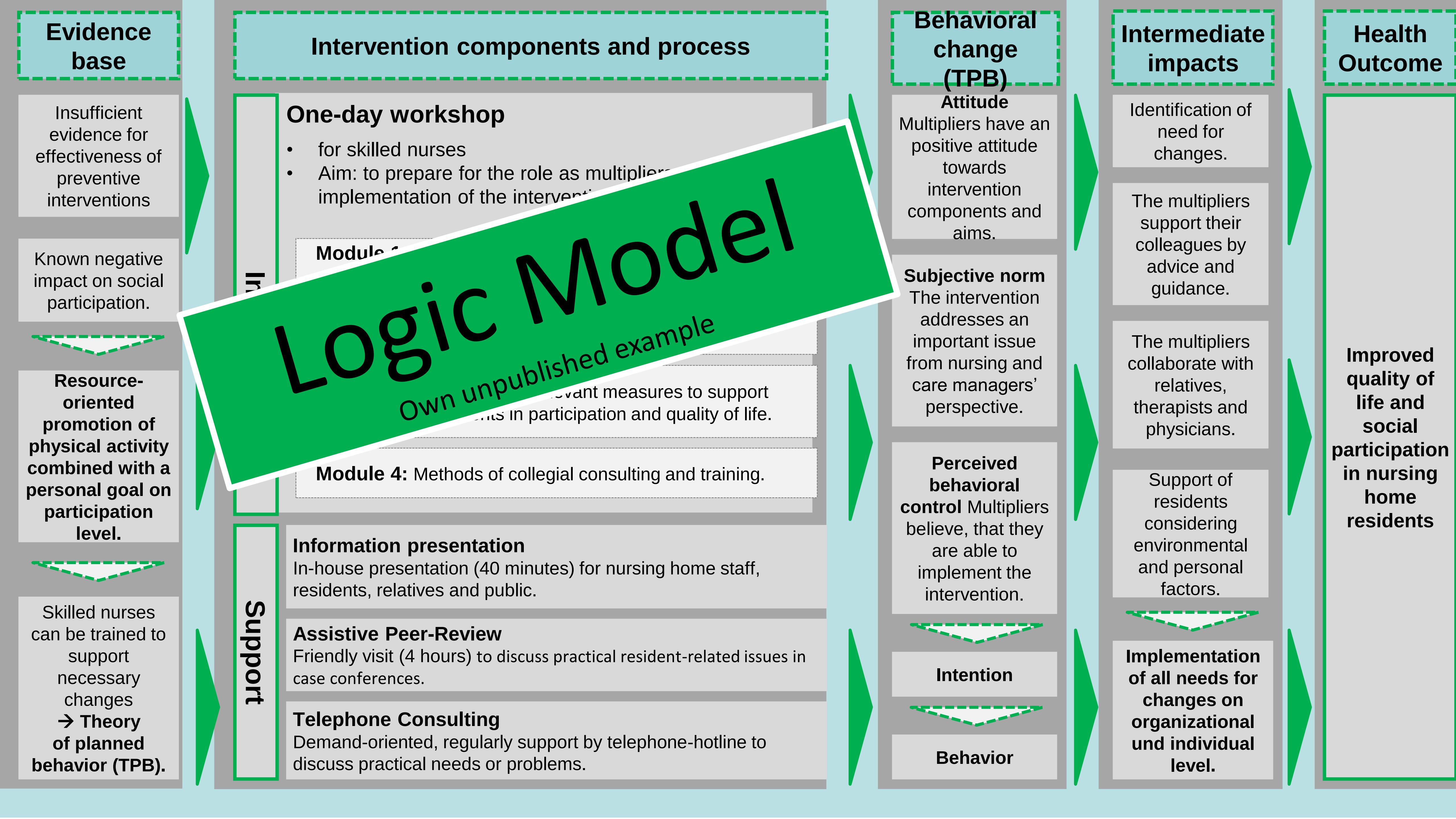


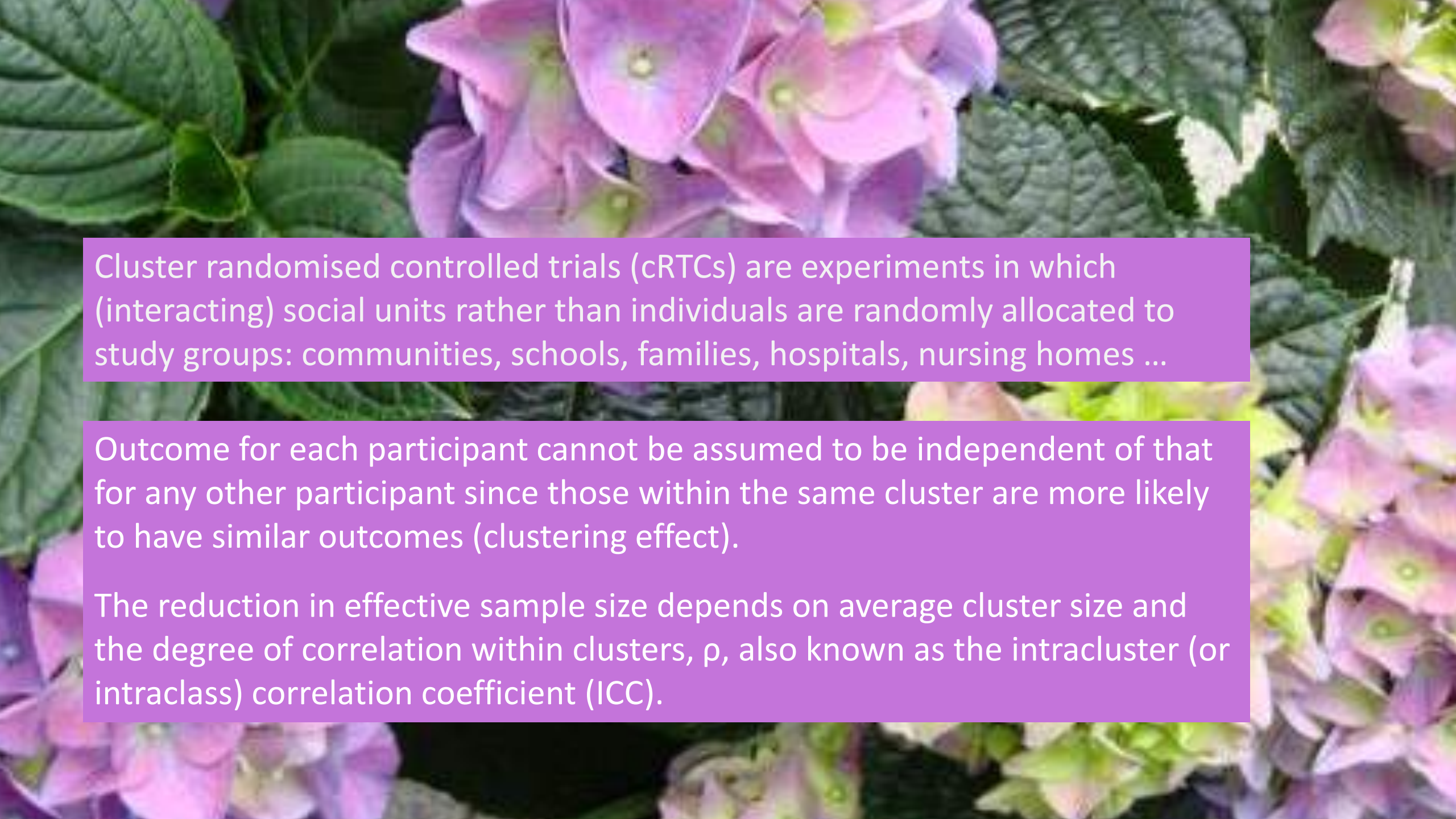
Figure 3 Methods and phases of engagement.

Figure 1 Key elements of the development and evaluation process



MRC 2008


Evidence base
Insufficient evidence for effectiveness of preventive interventions
Known negative impact on social participation.
Resource-oriented promotion of physical activity combined with a personal goal on participation level.
Skilled nurses can be trained to support necessary changes
→ Theory of planned behavior (TPB).
Intervention components and process
One-day workshop
for skilled nurses
Aim: to prepare for the role as multipliers
implementation of the interventi
Module 1
vant measures to support
in participation and quality of life.
Module 4: Methods of collegial consulting and training.
Support
Information presentation
In-house presentation (40 minutes) for nursing home staff, residents, relatives and public.
Assistive Peer-Review
Friendly visit (4 hours) to discuss practical resident-related issues in case conferences.
Telephone Consulting
Demand-oriented, regularly support by telephone-hotline to discuss practical needs or problems.
Logic Model
Own unpublished example
Behavioral change (TPB)
Attitude
Multipliers have an positive attitude towards intervention components and aims.
Subjective norm
The intervention addresses an important issue from nursing and care managers' perspective.
Perceived behavioral control Multipliers believe, that they are able to implement the intervention.
Intention
Behavior
Intermediate impacts
Identification of need for changes.
The multipliers support their colleagues by advice and guidance.
The multipliers collaborate with relatives, therapists and physicians.
Support of residents considering environmental and personal factors.
Implementation of all needs for changes on organizational und individual level.
Health Outcome
Improved quality of life and social participation in nursing home residents



Cluster randomised controlled trials (cRTCs) are experiments in which (interacting) social units rather than individuals are randomly allocated to study groups: communities, schools, families, hospitals, nursing homes …

Outcome for each participant cannot be assumed to be independent of that for any other participant since those within the same cluster are more likely to have similar outcomes (clustering effect).

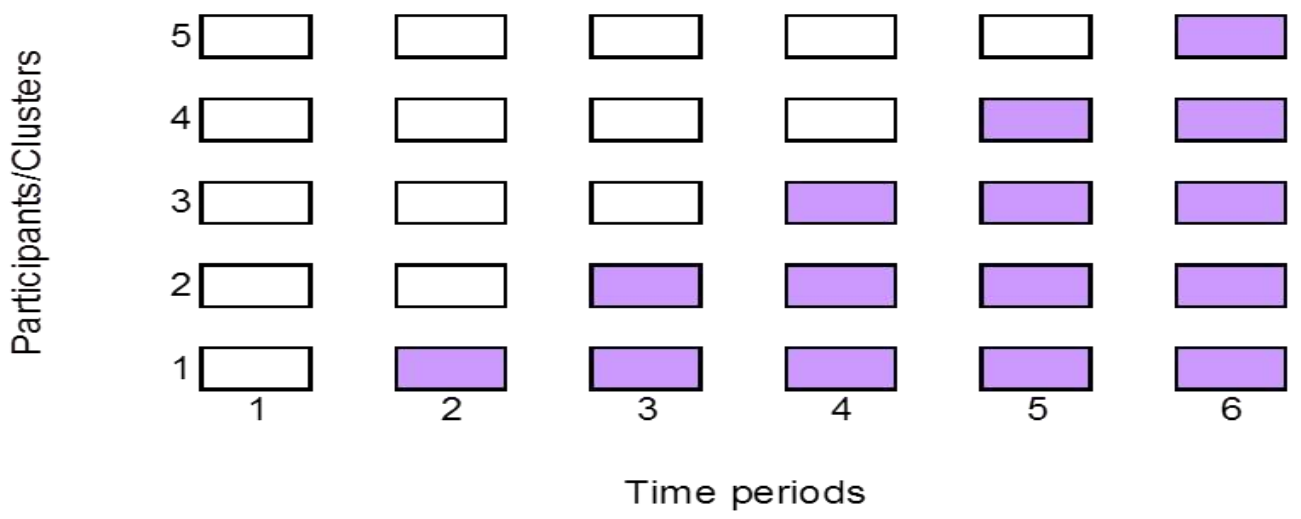
The reduction in effective sample size depends on average cluster size and the degree of correlation within clusters, ρ, also known as the intracluster (or intraclass) correlation coefficient (ICC).

Challenges of cRCT

- Cluster baseline imbalance (allocation techniques)
- Post-randomisation recruitment bias
- Attrition bias
- Blinding
- Ethical issues (e.g. waiver solutions)
- …

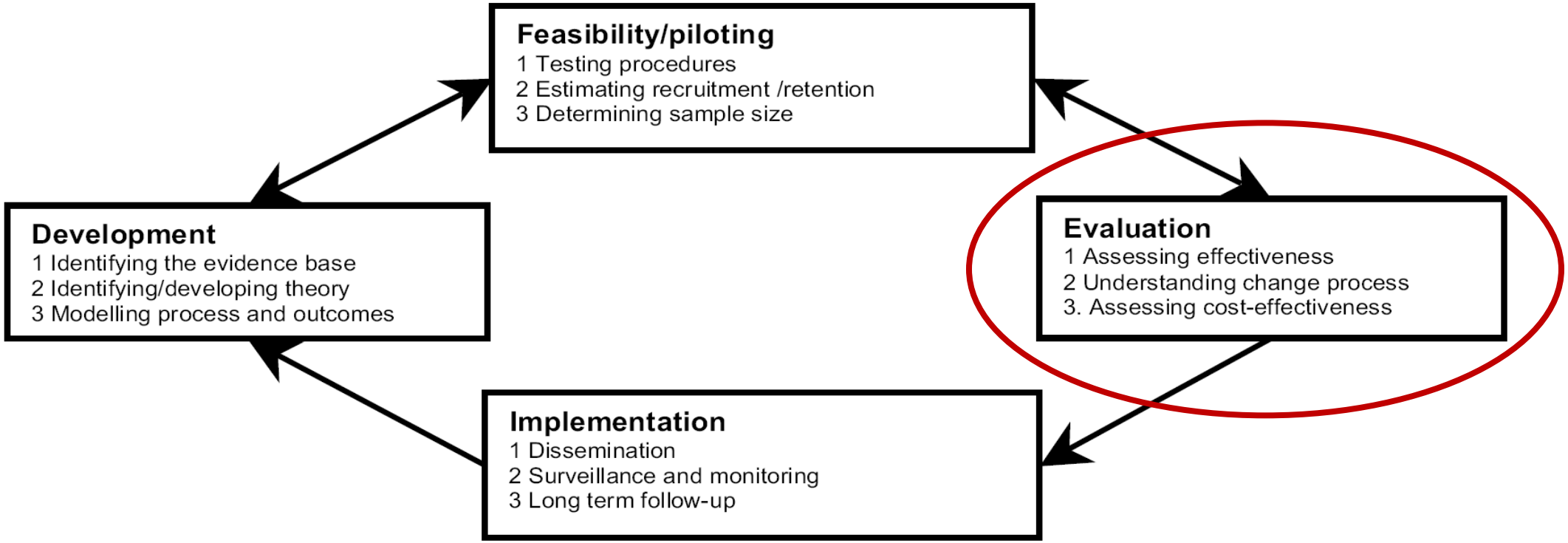
Stepped wedge design

Randomisation in terms of the period for receipt of the intervention → type of cluster crossover trial if the unit of randomisation is a cluster.



Shaded cells represent intervention periods
Blank cells represent control periods
Each cell represents a data collection point

Figure 1 Key elements of the development and evaluation process



MRC 2008

RESEARCH METHODS & REPORTING

BMJ 2015;350:h1258

Process evaluation of complex interventions: Medical Research Council guidance

Graham F Moore,[1] Suzanne Audrey,[2] Mary Barker,[3] Lyndal Bond,[4] Chris Bonell,[5] Wendy Hardeman,[6] Laurence Moore,[7] Alicia O'Cathain,[8] Tannaze Tinati,[3] Daniel Wight,[7] Janis Baird[3]

- A process evaluation is often highly valuable – providing insight into
  - why an intervention fails unexpectedly or
  - has unanticipated consequences or
  - why a successful intervention works and
  - how it can be optimised

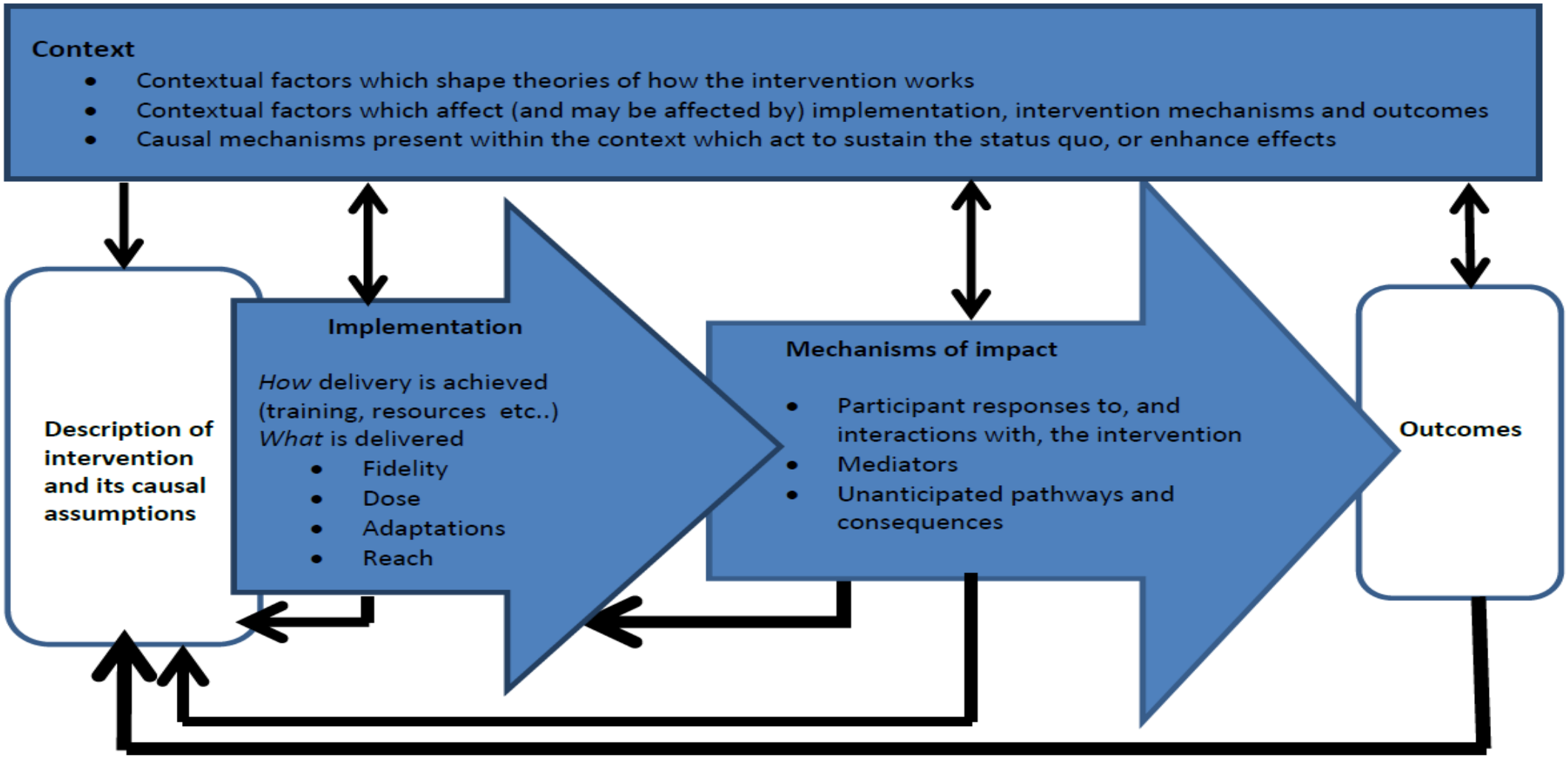
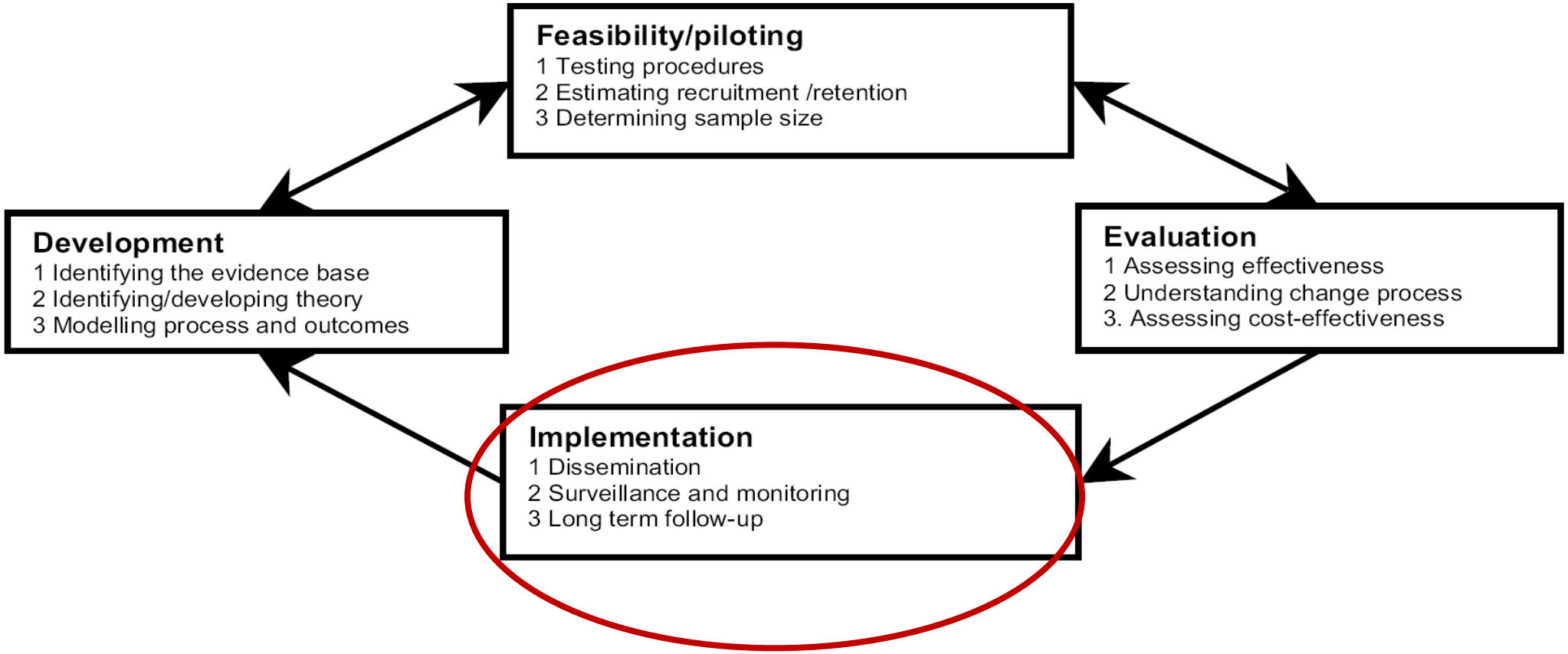


Figure 1. Key functions of process evaluation and relationships amongst them. Blue boxes represent components of process evaluation, which are informed by the causal assumptions of the intervention, and inform the interpretation of outcomes.

Figure 1 Key elements of the development and evaluation process



MRC 2008

„The results should be disseminated as widely and persuasively as possible, with further research to assist and monitor the process of implementation.”

MRC 2008

Diffusion	Spreading information and natural adoption by the target group of guidelines and working methods
Dissemination	Communication of information to care providers to increase their knowledge and skills; more active than diffusion; directed at a specific target group
Implementation	Introduction of an innovation in the daily routine; demands effective communication and removal of hindrances

Davis & Tailor-Vaisey, Can Med Assoc J 1997

http://actifcare.eu/

Actifcare

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Actifcare (ACcess to TImely Formal Care) is a European dementia research project that aims to analyse the pathways to care for people with dementia and their families, in an attempt to better understand the reasons for inequalities in access to healthcare. Focusing on the middle dementia stages, where typically transition from informal care alone to a combination of informal and formal home care takes place, Actifcare will

Reporting

Möhler *et al. Trials* (2015) 16:204
DOI 10.1186/s13063-015-0709-y

TRIALS

METHODOLOGY Open Access

Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare: revised guideline (CReDECI 2)

Ralph Möhler[1,2*], Sascha Köpke[3] and Gabriele Meyer[2]

BMJ

BMJ 2014;348:g1687 doi: 10.1136/bmj.g1687 (Published 6 March 2014)

RESEARCH METHODS & REPORTING

Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide


Thank you very much for listening!

Time for exercise!

Case study 1

- Ihre Forschungsgruppe hat in früheren Studien zu anderen Themen eher zufällig beobachtet, dass Pflegeheime in sehr unterschiedlichem Ausmaß Bewohner/-innen nach Sturzereignissen ins Krankenhaus überweisen. Das legt Interventionsbedarf nahe!

- Sie entwickeln auf Basis dieser Beobachtung eine RCT für das Setting Pflegeheim, in der die Bewohner/-innen entweder einer Kontrollgruppe mit üblicher Pflege/Versorgung zugewiesen werden oder optimierter Versorgung mit einem „Pathway“, der engen Arztkontakt nach Sturzereignis vorsieht und sorgfältiges „Watchful Waiting“ und somit bedächtiges Abwägen einer Krankenhauseinweisung.

- Dieser Plan ist □ angebracht □ nicht angebracht

Case study 2

- Ihre Forschungsgruppe will eine Studie zur Reduktion von Antipsychotika bei Menschen mit Demenz im Pflegeheim durchführen. Die vorpublizierte Evidenz ist eindeutig: In dieser Population schaden die Medikamente mehr als dass sie nützen. Sie haben eine komplexe Intervention entwickelt, bestehend aus Schulung und beratender Begleitung der Heime. Alle Einrichtungen, ob Kontrollgruppe oder Interventionsgruppe, erhalten ein kollegiales „peer review“ der Medikationslisten der teilnehmenden Bewohner/-innen mit Empfehlungsschreiben an die verschreibenden Ärzte/Ärztinnen. Der primäre Erfolgsparameter der Studie sind Bewohner/-innen mit mindestens einem Antipsychotikum. Sekundärer Endpunkt ist die Lebensqualität der Bewohner/-innen, die anhand des QUALIDEM Instruments direkt mit den Bewohnern/Bewohnerinnen erhoben wird.
- Sie beantragen einen „Waiver“ bei der Ethikkommission.

- Der „Waiver“ wird von den beteiligten Ethikkommissionen aus den drei teilnehmenden Regionen sehr wahrscheinlich □ erteilt □ nicht erteilt

Case study 3

- Ihre Forschungsgruppe hat eine komplexe Intervention entwickelt, um die soziale Teilhabe und Funktionsfähigkeit von Menschen mit Gelenkkontrakturen im Pflegeheim zu verbessern. Da sie in Ihren ausgiebigen Vorstudien die Akzeptanz und Machbarkeit der Intervention bereits belegt haben, möchten Sie jetzt von einer begleitenden prozessualen Evaluation absehen. Das spart Zeit und „Manpower“.

- Dieser Plan ist wissenschaftlich gesehen durchaus

  □ angemessen □ nicht angemessen