Quality control in behavioural trials: Assessing fidelity and processes of change

Facilitators: Prof Molly Byrne and Dr Elaine Toomey

Health Behaviour Change Research Group,

School of Psychology, NUI Galway, Ireland

ibtn
international
behavioural
trials network

International Behavioural Trials Network Conference
26th May 2018

NUI Galway
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Overview

Learning objectives

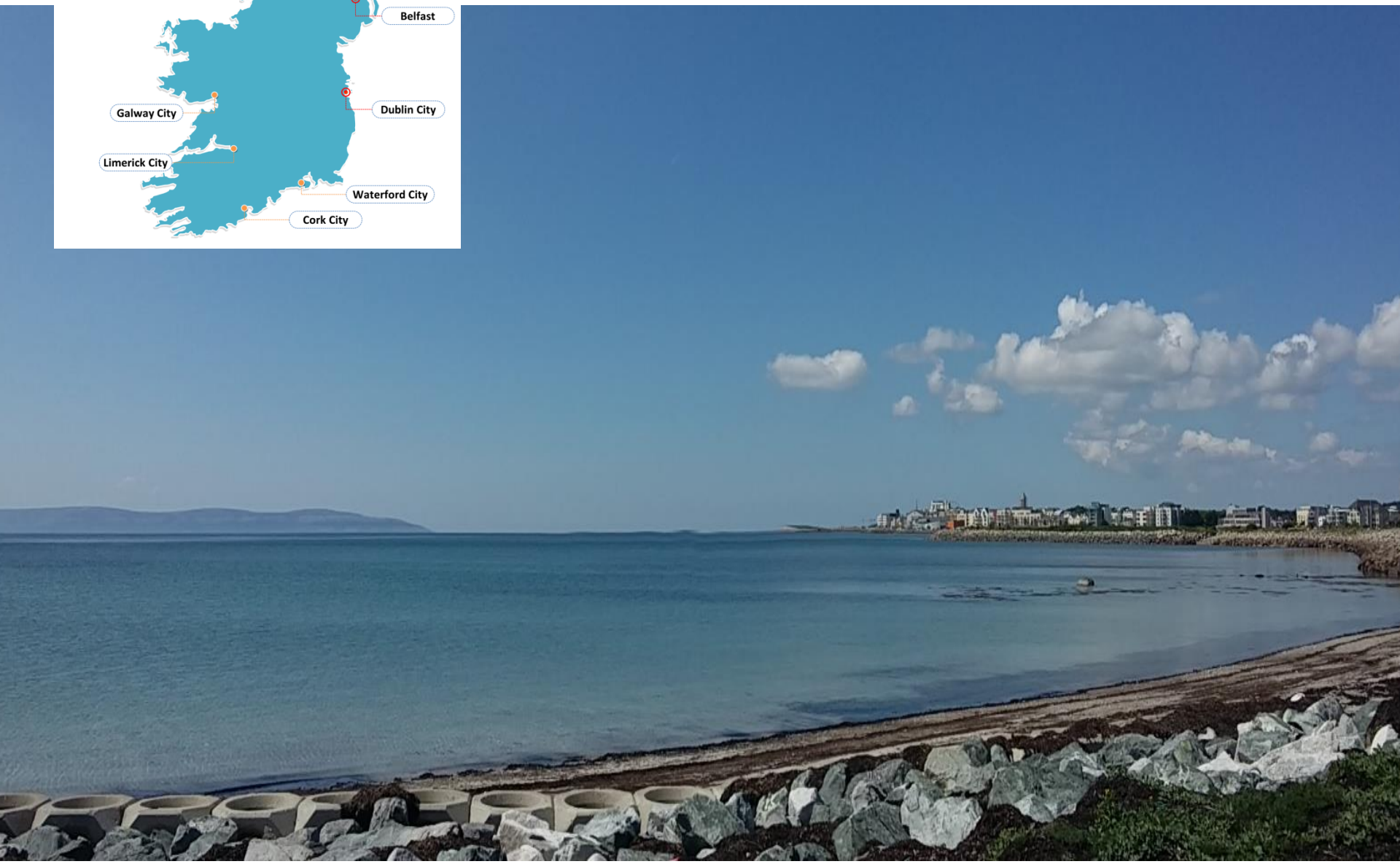
To introduce and develop knowledge and skills in addressing intervention fidelity and processes of change within behavioural trials

By the end of this workshop you should be able:

- To describe approaches to the development of theory-based behaviour change interventions and outline strategies to measure mechanisms of action within behavioural trials
- To introduce participants to potential strategies for assessing and enhancing intervention fidelity within behavioural trials
- To give participants an opportunity to apply learning to examples of behavioural trials, as well as considering strategies for application to their own projects

Workshop outline

9:00		Introductions and workshop overview	MB & ET
9:15		So what's the problem...? Importance of intervention fidelity and processes of change within behavioural trials	MB & ET
9:45	Objective 1	Development of theory-based behaviour change interventions and strategies to measure mechanisms of action	MB EXERCISE 1
10:30		Break	
10:45	Objective 2	Strategies for assessing and enhancing intervention fidelity	ET EXERCISE 2
11:45	Objective 3	Application to worked examples and Q&A	MB & ET
12:00		Finish	


Legend
Capital
Major cities
Belfast
Dublin City
Galway City
Limerick City
Waterford City
Cork City

HRB Research Leaders Award 2013

To establish the **Health Behaviour Change Research Group** at NUI Galway, to promote the routine application of Behavioural Science to the development and evaluation of behavioural interventions within population and health-services research

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Our Vision

To improve population health by developing and promoting an evidence-based approach to health behaviour change interventions

We aim to

- **Lead** the behavioural research agenda, by identifying and pursuing behavioural research priorities which impact on health.
- **Develop, pilot and evaluate** complex interventions, using evidence-based behavioural theory and employing theory-linked behaviour change techniques.
- **Advance** the science of behaviour change and critically evaluate the evidence for different approaches to behaviour change.
- **Build** capacity by establishing a critical mass of excellent researchers, delivering innovative training and creating a vibrant learning environment.
- **Impact** on tangible health outcomes through development, evaluation and implementation of behaviour change interventions.

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Our research topics include

- Cardiovascular disease
- Diabetes
- Hand hygiene in healthcare settings
- Infant feeding
- Medication adherence
- Multimorbidity
- Obesity
- Physical activity
- Primary care

Our methodological strengths are

- Complex interventions
- Conduct and reporting of trials
- Development of core outcomes sets
- Implementation science
- Qualitative research within trials
- Stakeholder engagement and consensus building
- Systematic reviews
- Fidelity assessment / Process evaluation

Capacity building

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Designing Effective Interventions for Health Behaviour Change: An Introduction

Monday 16th October 2017
School of Psychology, NUI Galway (10am – 5pm)

Participants will learn about, and practice using, methods for designing and evaluating behavioural interventions. Suitable for researchers, practitioners, policy makers and students interested in behaviour change.

For more information, visit www.nuigalway.ie/hbcrg

Clinic Facilitators: Dr Molly Byrne and Dr Jenny Mc Sharry
Health Behaviour Change Research Group, NUI Galway

QUESTS

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Qualitative Evidence Synthesis: An Introduction

One Day Workshop
Wednesday 26 October 2016,
10am – 5pm
NUI Galway

In this workshop, participants will have an opportunity to learn about, and practice using, qualitative synthesis methods. Participants will gain an overview and understanding of different methods involved in conducting a qualitative review. The workshop is for researchers, practitioners, policy makers and students interested in evidence synthesis of qualitative data.

Details and Registration, visit: http://tinyurl.com/zyjyg5f
For further information, please contact Elaine Toomey
E: elaine.toomey@nuigalway.ie T: 091 49 4458

QUESTS Qualitative Research in Trials Centre, Aras Moyola, NUI Galway www.quests.ie
Health Behaviour Change Research Group, School of Psychology, NUI Galway www.nuigalway.ie/psy

Limited Places Available!

To register now, please visit http://tinyurl.com/zyjyg5f

Cost €100 (€40 students)

Supported by HRB Health Research Board

In association with TMRN

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Registration now open! Designing Effective Interventions for Health Behaviour Change: Intensive Follow-Up Workshop

Friday 16th February 2018
School of Psychology, NUI Galway (10am – 5pm)

Workshop Facilitators: Dr Molly Byrne and Dr Jenny Mc Sharry, Health Behaviour Change Research Group, NUI Galway

The follow-up workshop will provide mentoring and support to a small group of researchers, practitioners and policy makers currently engaged in the development and evaluation of behaviour change interventions.

For more information, visit www.nuigalway.ie/hbcrg
To register, visit tinyurl.com/HBCRG2018

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Seminar Series 2018

21 Feb: The Why, What and How of Physical Activity and Sedentary Behaviour Measurement
Dr Kieran Dowd, Athlone Institute of Technology

14 Mar: Men on the Move: The story of a community based PA programme for inactive men
Dr Paula Carroll, Waterford Institute of Technology

18 Apr: Video Ethnographies as Qualitative Interview Discussion Tools; an example from practice
Dr Hannah Delaney

09 May: Promoting physical activity in long term conditions – rheumatoid arthritis
Dr Louise Larkin, University of Limerick

1.00-2.00pm, Room G065, School of Psychology, NUI Galway
See www.nuigalway.ie/hbcrg @hbcrg

DECIPHer Development and Evaluation of Complex Interventions for Public Health Improvement

HEALTH BEHAVIOUR CHANGE RESEARCH GROUP

FREE One-day workshop on Process Evaluations of Complex Interventions in Health

Supported by: BITSS

Thursday 7th September 2017
School of Psychology, NUI Galway (10am – 4.30pm)

Participants will learn about, and practice using, theory and methods for conducting process evaluations of complex health interventions. Suitable for researchers, practitioners, policy makers and students. Places limited!

Closing date for applications: Friday 11th August 12pm!

For more information, visit www.nuigalway.ie/hbcrg

Workshop Facilitators: Dr Graham Moore and Dr Rhiannon Evans
DECIPHer Cardiff (UKCRC Public Health Research Centre of Excellence)

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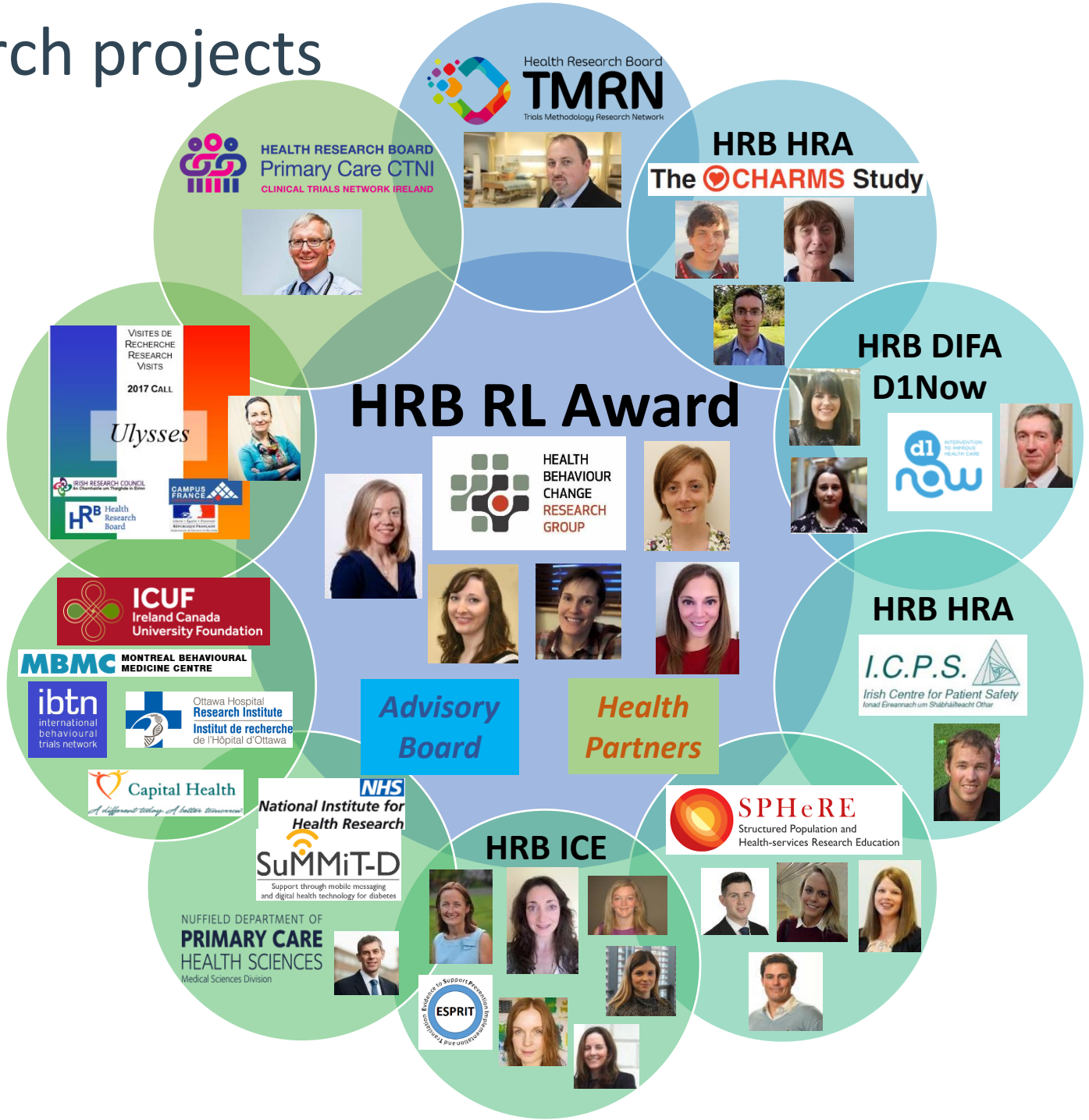
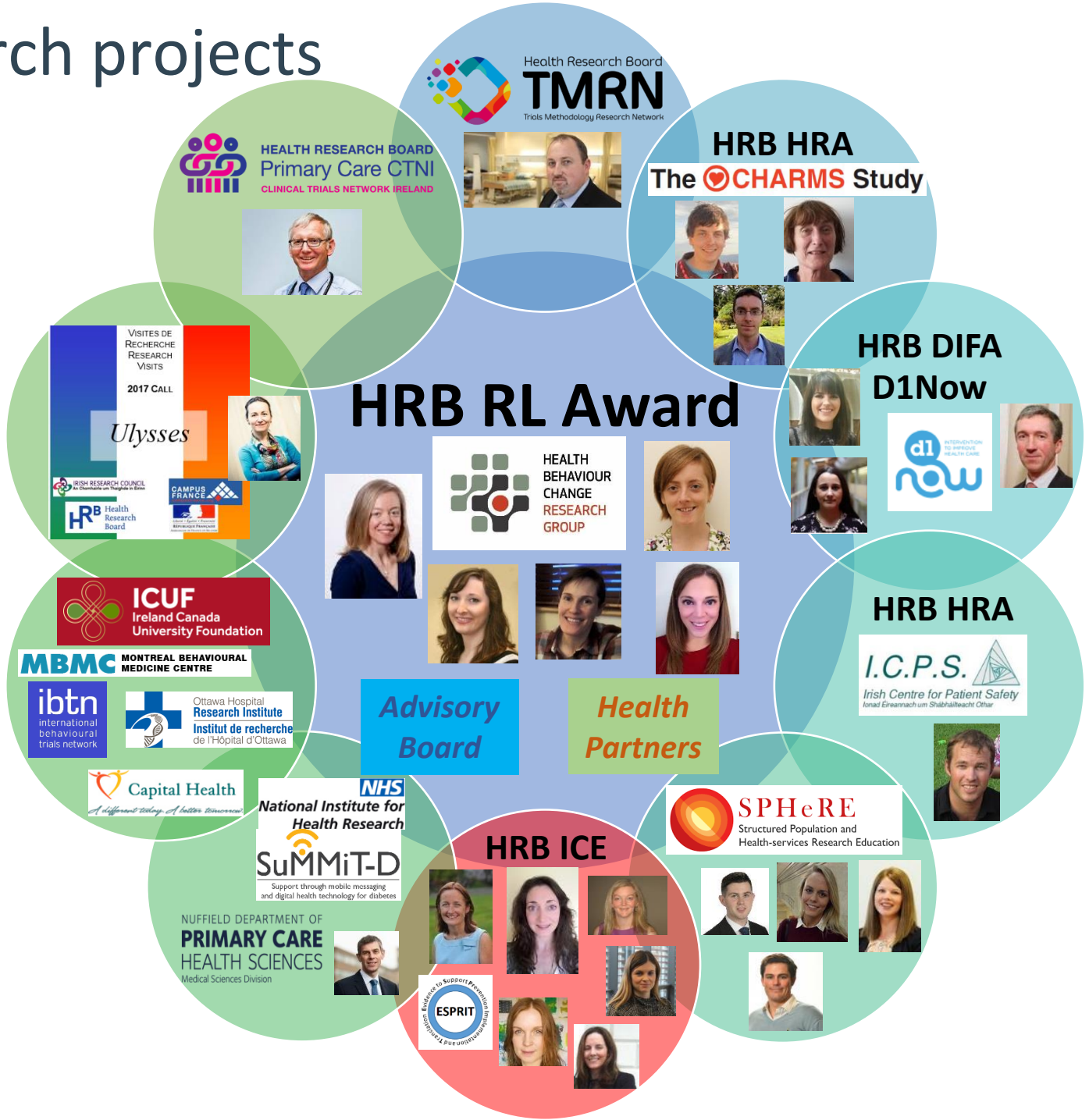
For more on the HBCRG: valerie.parker@nuigalway.ie or molly.byrne@nuigalway.ie

Research projects



Research projects



HRB Interdisciplinary Capacity Enhancement (ICE) Award 2015

CHErIsH
Choosing Healthy Eating for Infant Health

'Develop and evaluate an infant feeding intervention to prevent childhood obesity in primary care'

Dr. Karen Matvienko-Sikar
Health Psychology

Dr. Michelle Queally
Health Economics

Dr. Elaine Toomey
Implementation Science/
Intervention fidelity

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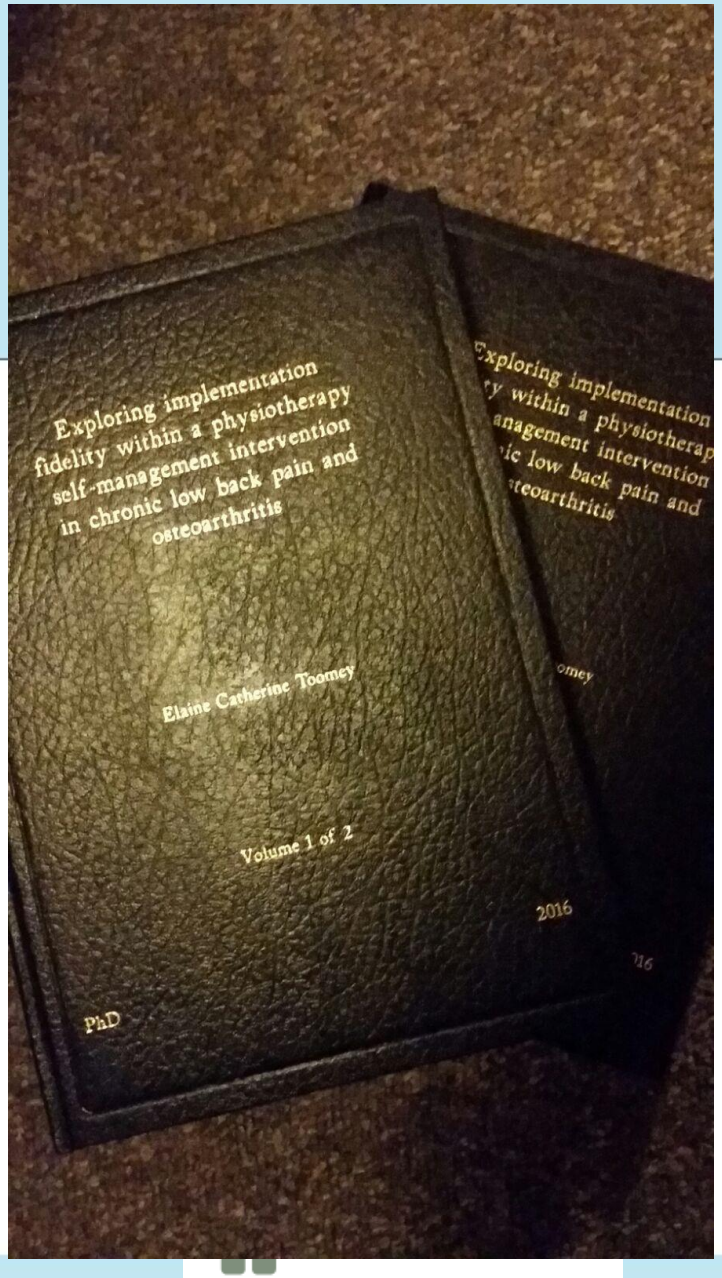
PhD research

‘Exploring implementation fidelity within a physiotherapy self-management intervention in chronic low back pain and osteoarthritis’



The CHARMS Study

Implementation science, intervention fidelity, process evaluation

Physiotherapy, chronic pain

Cardiovascular disease

Public health, childhood obesity

Health behaviour change, complex interventions

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School Institute Name to go here

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WHO
ARE
YOU?

So what's the problem?

The Formula for Good Health

0 Cigarettes

5 Servings of fruits and vegetables per day

10 Minutes of silence, relaxation or meditation per day

30 Body Mass Index < 30 kg/m^2

150 Minutes of exercise per week
(e.g., brisk walking or equivalent)

Place a ✓ for what you already do and an ✗ for what you commit to working on.

Eastern Plumas Health Care
"People Helping People."

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OPEN ACCESS Freely available online PLOS MEDICINE

Combined Impact of Health Behaviours and Mortality in Men and Women: The EPIC-Norfolk Prospective Population Study

Kay-Tee Khaw[1*], Nicholas Wareham[2], Sheila Bingham[3], Ailsa Welch[1], Robert Luben[1], Nicholas Day[1]

1 Department of Public Health and Primary Care, Institute of Public Health, University of Cambridge School of Clinical Medicine, Cambridge, United Kingdom, 2 Medical Research Council, Epidemiology Unit, Cambridge, United Kingdom, 3 Medical Research Council, Dunn Nutrition Unit, Cambridge, United Kingdom

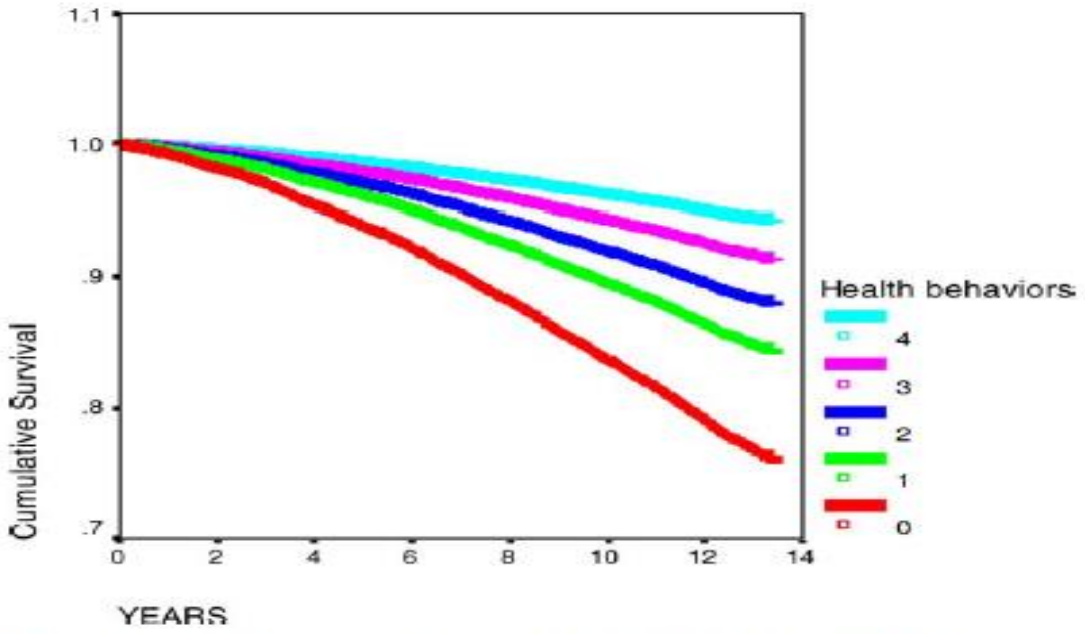

Figure 1. Survival Function According to Number of Health Behaviours in Men and Women Aged 45–79 Years without Known Cardiovascular Disease or Cancer, Adjusted for Age, Sex, Body Mass Index and Social Class, EPIC-Norfolk 1993–2006

doi:10.1371/journal.pmed.0050012.g001

Health Behaviour	How Scored
Smoking habit	Nonsmoker = 1
Fruit and vegetable intake	Five servings or more daily as indicated by blood vitamin C = ≥50 nmol/l = 1
Alcohol intake	One or more, but less than 14 units, a week = 1. One unit = approximately 8 g of alcohol; i.e., one glass of wine, one small glass of sherry, one single shot of spirits, or one half pint of beer
Physical activity	Not inactive = 1; i.e., if sedentary occupation at least half an hour of leisure time activity a day; e.g., cycling, swimming; or else a nonsedentary occupation with or without leisure-time activity

Conclusions

Four health behaviours combined predict a 4-fold difference in total mortality. The mortality risk for those with four compared to zero health behaviours was equivalent to being 14 y younger in chronological age.

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Behaviour change interventions can be effective

A gender-sensitised weight loss and healthy living programme for overweight and obese men delivered by Scottish Premier League football clubs (FFIT): a pragmatic randomised controlled trial

Lancet 2014; 383: 1211–21

Kate Hunt, Sally Wyke, Cindy M Gray, Annie S Anderson, Adrian Brady, Christopher Bunn, Peter T Donnan, Elisabeth Fenwick, Eleanor Grieve, Jim Leishman, Euan Miller, Nanette Mutrie, Petra Rauchhaus, Alan White, Shaun Treweek

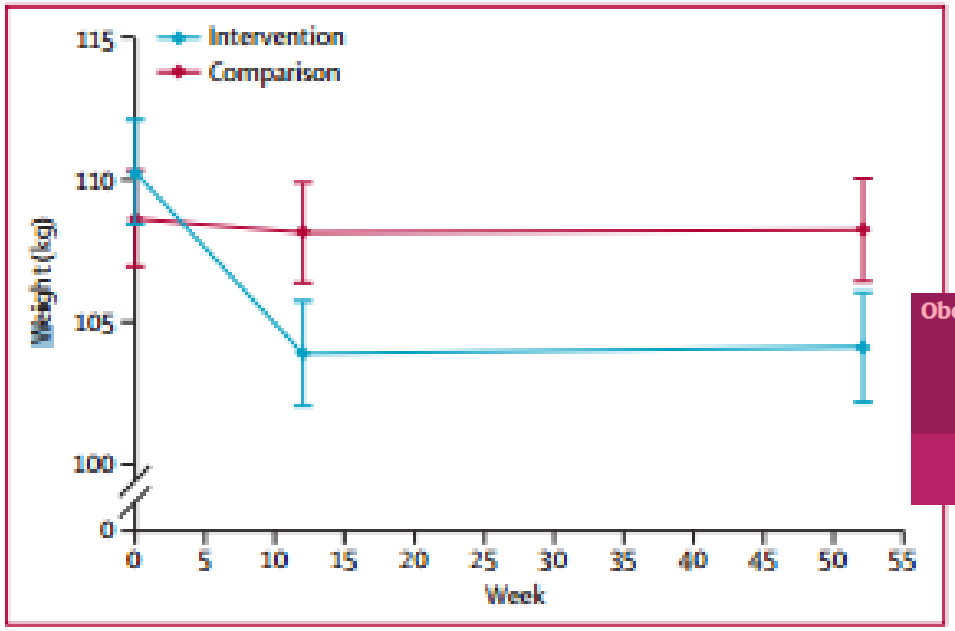

Figure 2: Mean weight (kg, 95% CI) in participants allocated to the Football Fans in Training weight loss programme or waiting list comparison group 12 weeks and 12 months after baseline measurement.

theguardian
Winner of the Pulitzer prize

Obesity

Football fans get FFIT through Scottish premiership scheme tackling obesity

St Johnstone fan used to gasp going up stairs - now Football Fans in Training scheme has him climbing mountains

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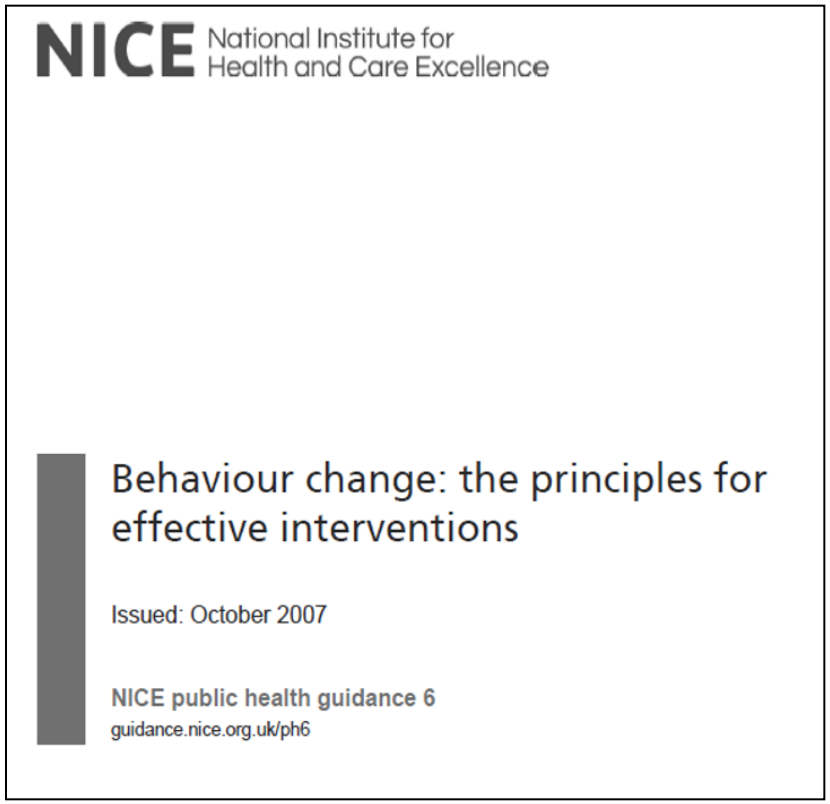

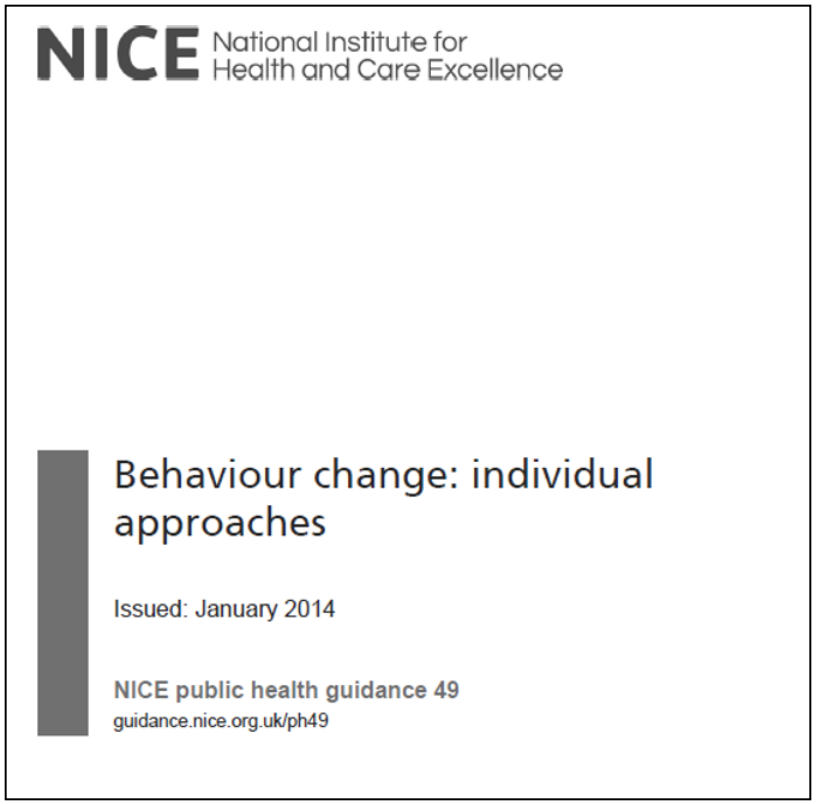

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NICE recommendations

Plan & evaluate interventions carefully

- Take account of local and national context
- Use evidence-based techniques
- Describe mechanisms of change – how the intervention works!

Train practitioners in evidence-based behaviour change skills & competencies

Effective interventions:

- Target multiple 'levels': individual, community and population
- Individual level:
  - Provide realistic information about outcomes and emphasise personal salience;
  - Enhance self-efficacy;
  - Focus on immediate, tangible positive aspects of outcomes;
  - Assist with planning and goal setting;
  - Feedback, monitoring and structured follow up;
  - Employ social support and utilise people's reference groups/significant others;
  - Increasing motivation through motivational interviewing when resistance to change
  - Use 2+ strategies

Behaviour change is complicated

What's the problem....?

Many interventions designed according to the ISLAGIATT principle

It **S**eemed **L**ike **A** **G**ood **I**dea **A**t **T**he **T**ime

Patient has changed their behaviour!
Intervention worked!

But how did it work?
Can we do it again?
Can we train others to do the same?

Need for a common language
Biomedicine vs Behavioural Science

Varenicline (JAMA 2006)

Intervention content

- Varenicline titrated to 1 mg twice daily (n = 344) or bupropion SR titrated to 150 mg twice daily (n = 342) or placebo (n = 341) for 12 weeks

Mechanism of action

Behaviour counselling (Cochrane 2005)

Intervention content

- Review smoking history & motivation to quit
- Help identify high risk situations
- Generate problem-solving strategies
- Non-specific support & encouragement

Mechanism of action

Which of these would you find easier to replicate?

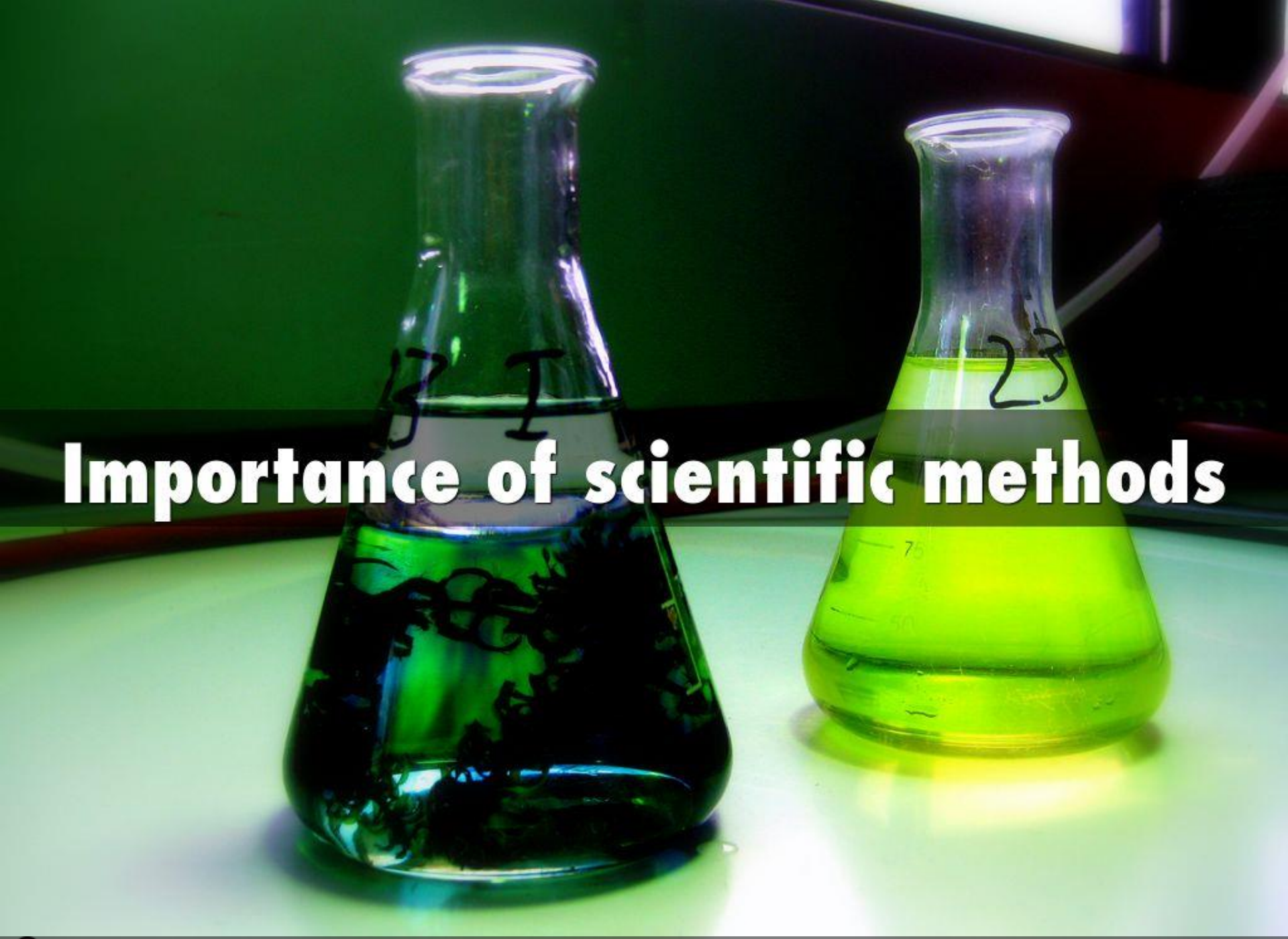
Which of these could you explain to someone else?

Summary: So what's the problem?

- Poor definition of interventions
  - Limited ability to develop science/theory
  - Limited ability to generalise findings
- No understanding of mechanisms of change
  - If effective, unclear why it worked, can't replicate...
  - If ineffective, not sure why...

– NEED TO ARTICULATE AND TEST CAUSAL MECHANISMS OF CHANGE

Importance of scientific methods



How to improve behaviour change interventions

1. **Specify** target behaviour precisely
2. Use behavioural **theory** to develop interventions **systematically**
3. Describe and measure **mechanisms** through which these work
4. Specify **behaviour change techniques**, linking these to theory
5. Improve **reporting**, using standardised, shared terminology
6. Facilitate **combining evidence** in systematic reviews to **inform practice**

Why and how do these interventions work?

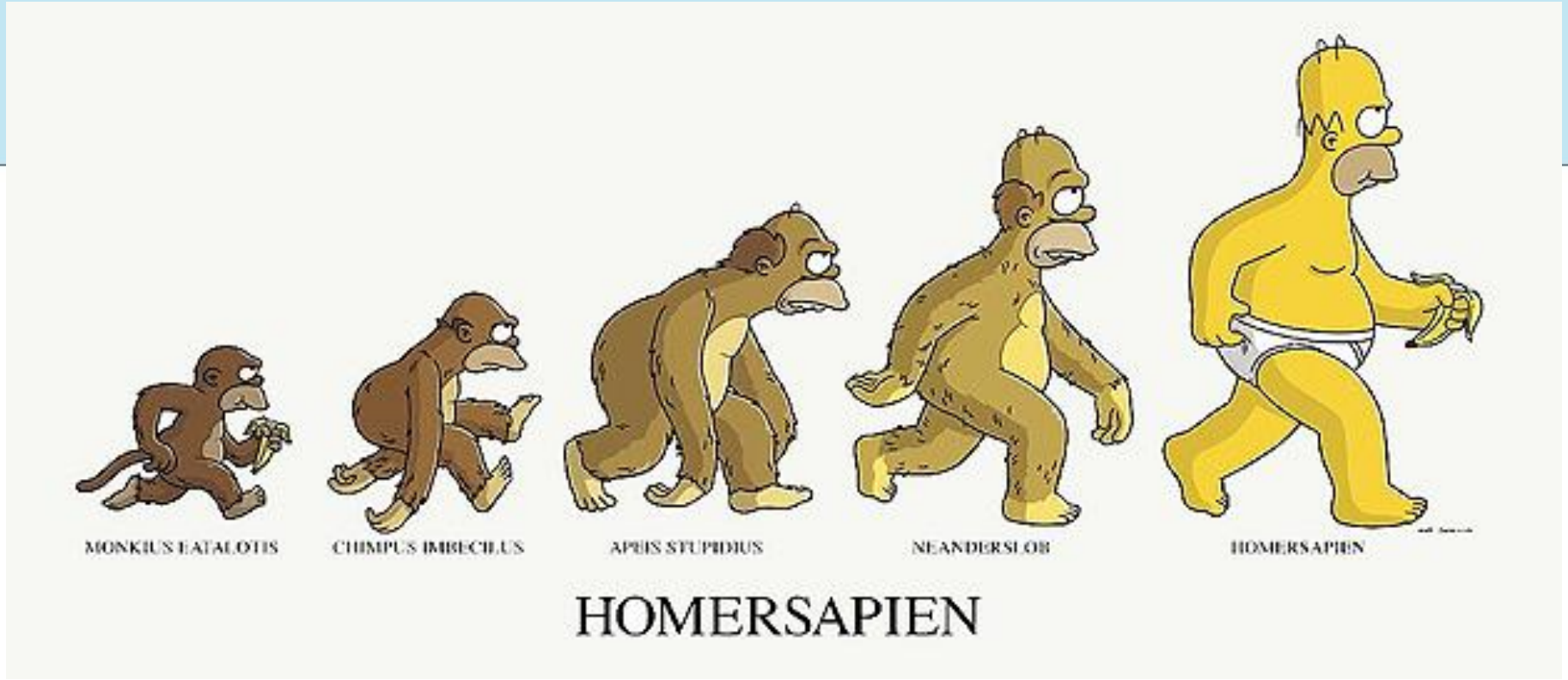
Or not?

Intervention fidelity

- Intervention fidelity – ‘extent to which intervention is implemented as intended by developers’
- Key in understanding why or how interventions succeed or fail
- Key component of MRC process evaluations of complex interventions
  - Mechanisms of action
  - Context
  - Fidelity

Intervention fidelity

- Intervention fidelity…. **OR**
- Treatment fidelity, treatment integrity, intervention adherence, implementation fidelity, programme fidelity, programme integrity, procedural reliability, therapist adherence/competence…..



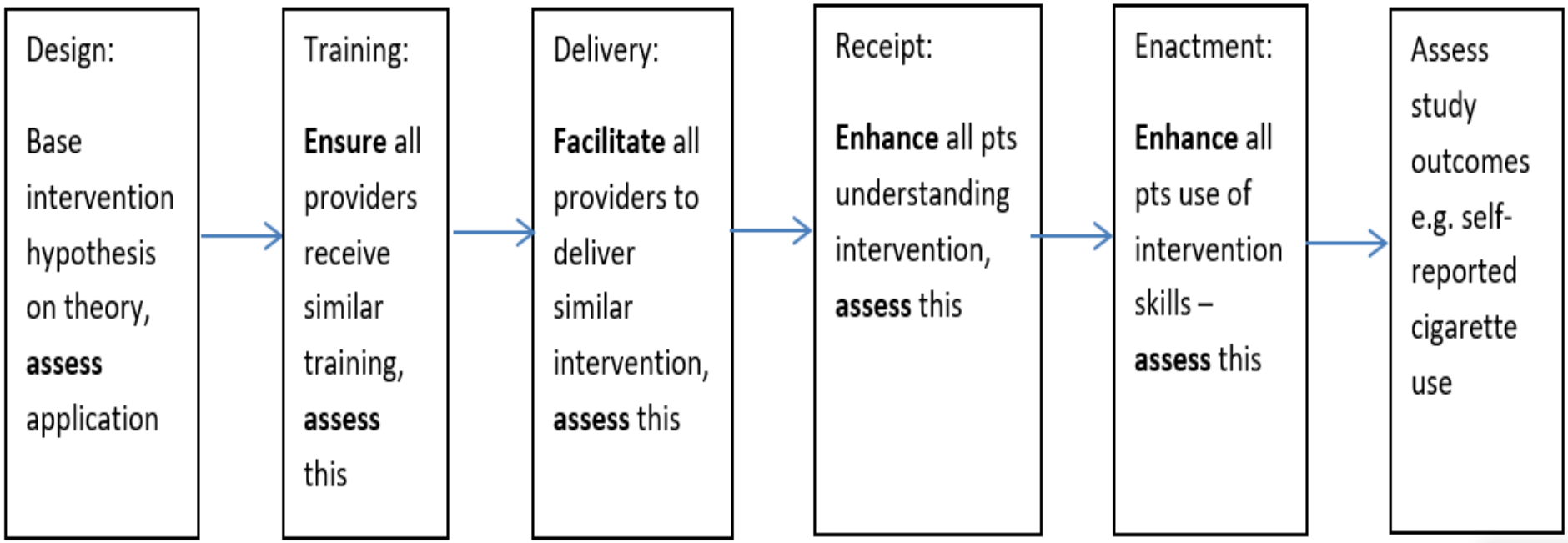
More than just the delivery….

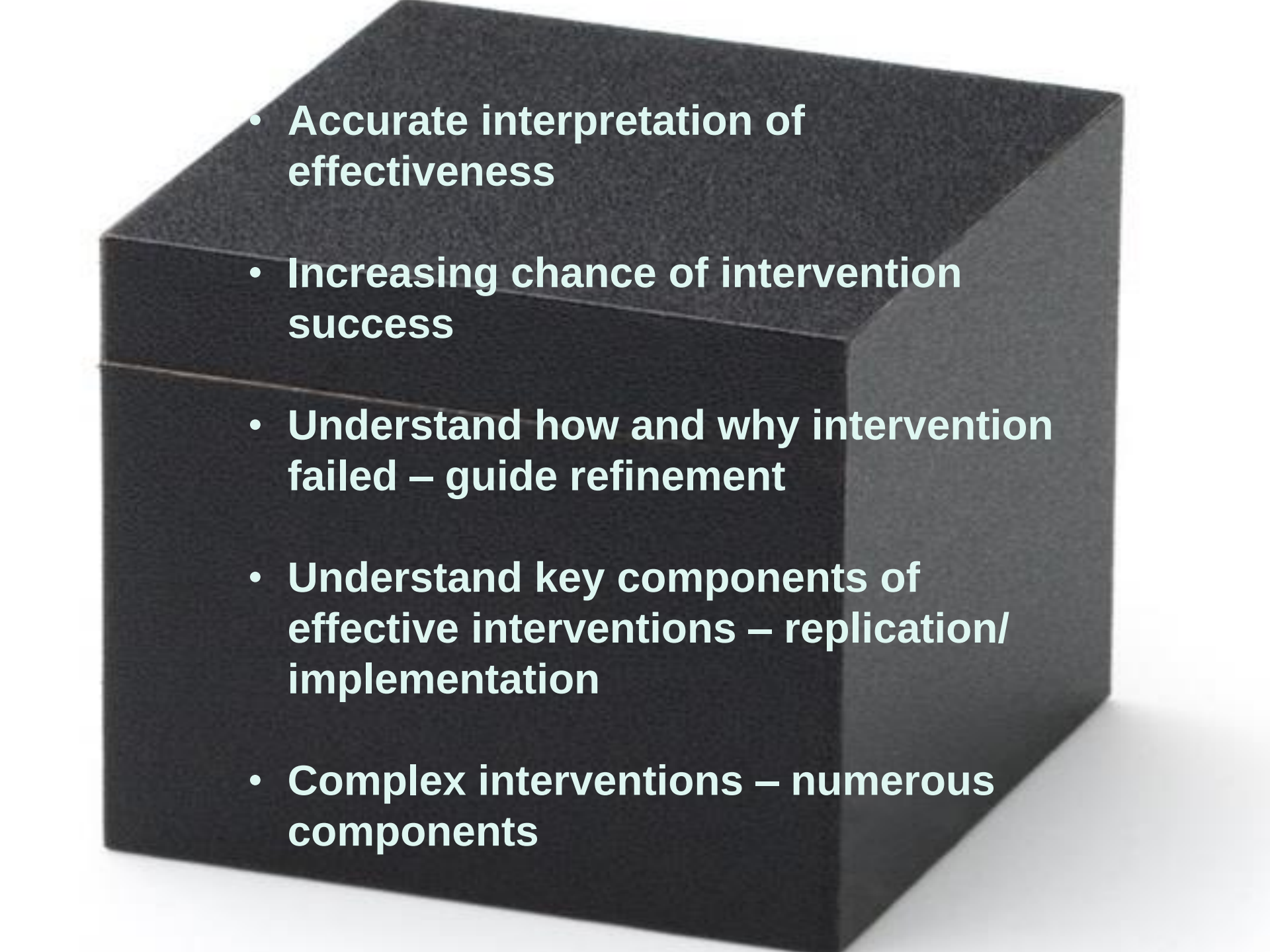
Intervention without fidelity procedures:

Inform providers of what the intervention is and what is expected of them: e.g. provision of information session and nicotine patches

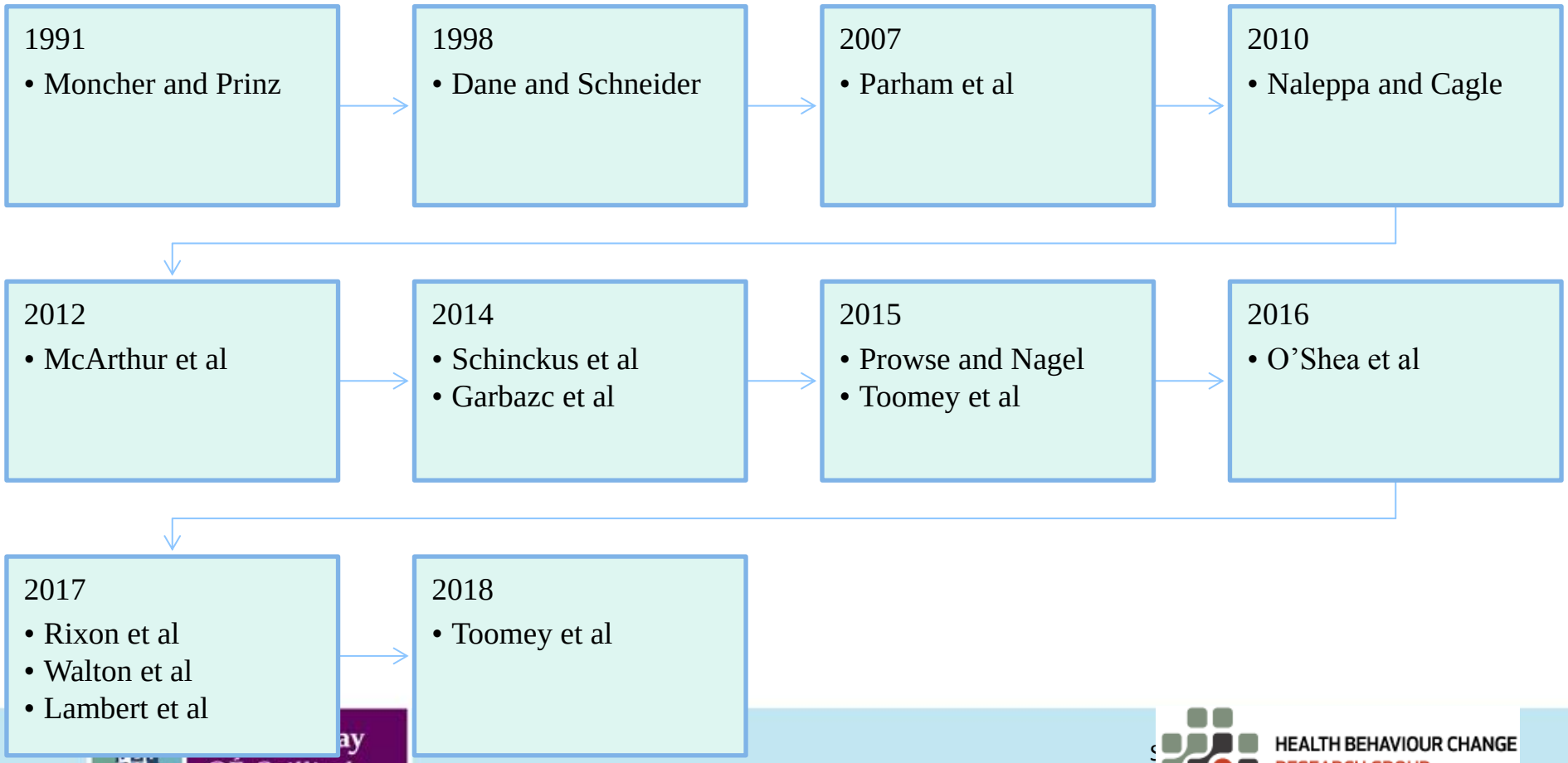
Assess study outcomes e.g. self-reported cigarette use

Intervention with fidelity procedures:




• Accurate interpretation of effectiveness
• Increasing chance of intervention success
• Understand how and why intervention failed – guide refinement
• Understand key components of effective interventions – replication/ implementation
• Complex interventions – numerous components

What are the gaps?



Why??

- Several barriers previously identified
  - Time, resources, lack of guidance/knowledge, lack of editorial requirement, lack of buy-in

- Specific to psychotherapy and educational psychology research (Perepletchikova et al. 2009; Cochrane and Laux 2008)

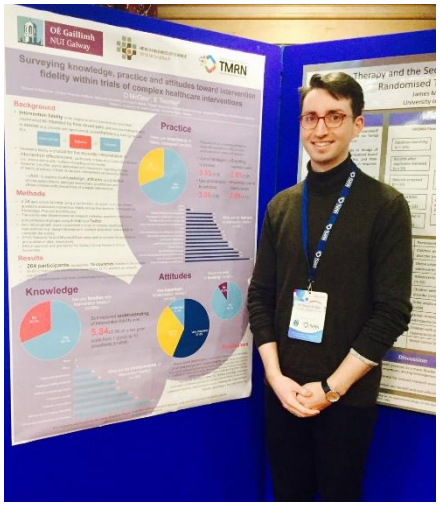
Surveying intervention fidelity within trials of complex healthcare interventions

To explore **knowledge, practice, attitudes** and **barriers and enablers** to addressing intervention fidelity amongst researchers, triallists and healthcare professionals with **experience of trials of complex healthcare interventions**

Mr. Daragh McGee[1], Dr. Fabiana Lorencatto[1], Dr. Karen Matvienko Sikar[1], Dr. Elaine Toomey[1]

[1]National University of Ireland Galway, [2]University College London, [3]University College Cork

Health Research Board
TMRN
Trials Methodology Research Network



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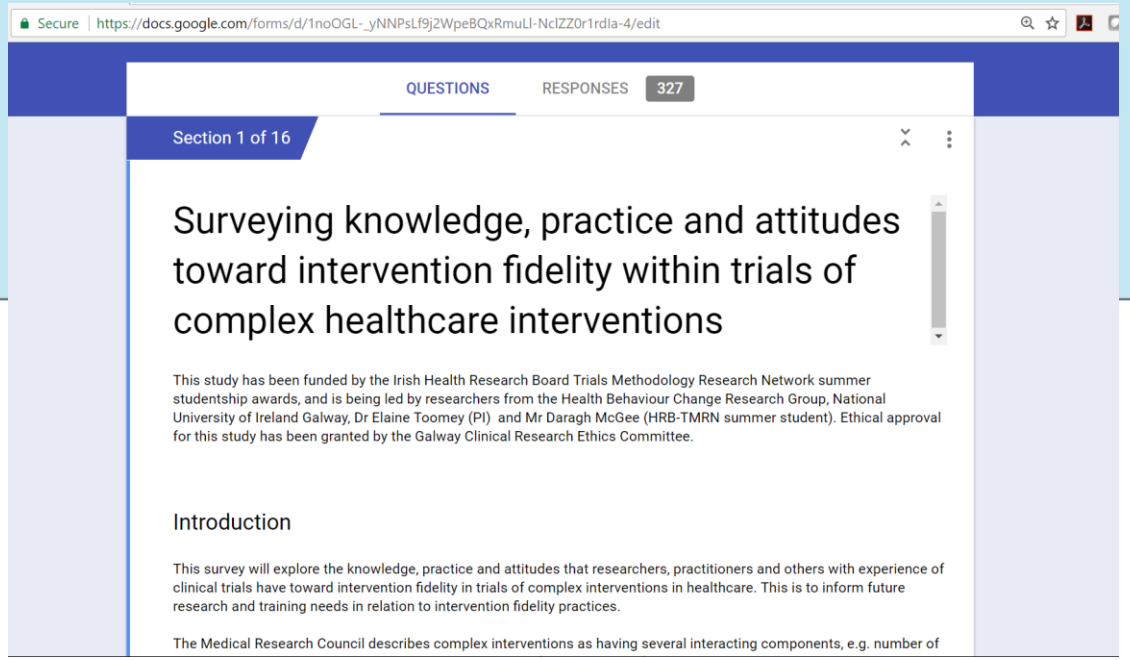
Methods



- Online survey
- (www.google.com/forms)

- Inclusion criteria:
  - Researchers, triallists, healthcare professionals with research experience of trials of complex healthcare interventions
  - All areas of healthcare
- Exclusion criteria:
  - Study subjects/patient participants
  - Experience of drug/pharma trials only

Knowledge

12. **Are you familiar with the term ir**
Mark only one oval.

Yes *Skip to question 1*

No *Skip to question 1*

13. **Which of the following do you think are components of intervention fidelity? (Tick all that apply)**
Check all that apply.

Ensuring that interventions adequately reflect their underlying theory (e.g. Theory of Planned Behaviour) or hypothesised mechanisms of action (e.g. using mediation analysis)

Ensuring adequate difference between the treatment and control groups (i.e. treatment differentiation)

n (e.g. doctors, therapists, allied health

ntion providers is conducted as intended

nts or patients as it was designed

s received (e.g. attended) and understood the

ntervention skills or behaviours in real life

28. **Please list what you feel are the three most important barriers to assessing, enhancing addressing or reporting intervention fidelity in trials of complex healthcare interventions.**

29. **Which, if any, of the following do you think may be enablers/facilitators to enhancing, addressing or reporting intervention fidelity in trials of complex healthcare interventions? (Tick all that apply)**
Check all that apply.

Clear understanding of the definition of intervention fidelity

Good knowledge of how to assess or enhance it

Availability of validated tools or checklists for assessment or enhancement

Availability of practical guidance on strategies and how to adapt them to individual trials

Perceived importance by researchers

Perceived importance by academic journals

Availability of reporting criteria specific to intervention fideli

Space allowances/reporting requirements within academic

Accessibility of methodologists or people with skills to impl
strategies

Funding or monetary resources

readability

Practice

16. **In your experience of trials of complex interventions, was intervention fidelity ever assessed (i.e. the use of strategies to assess fidelity to the intervention) or enhanced (i.e. the use of strategies to improve fidelity to the intervention)?**
Mark only one oval.

Yes *Skip to question 17.*

No *Skip to question 23.*

Results - participants

- 264 participants – 15 countries

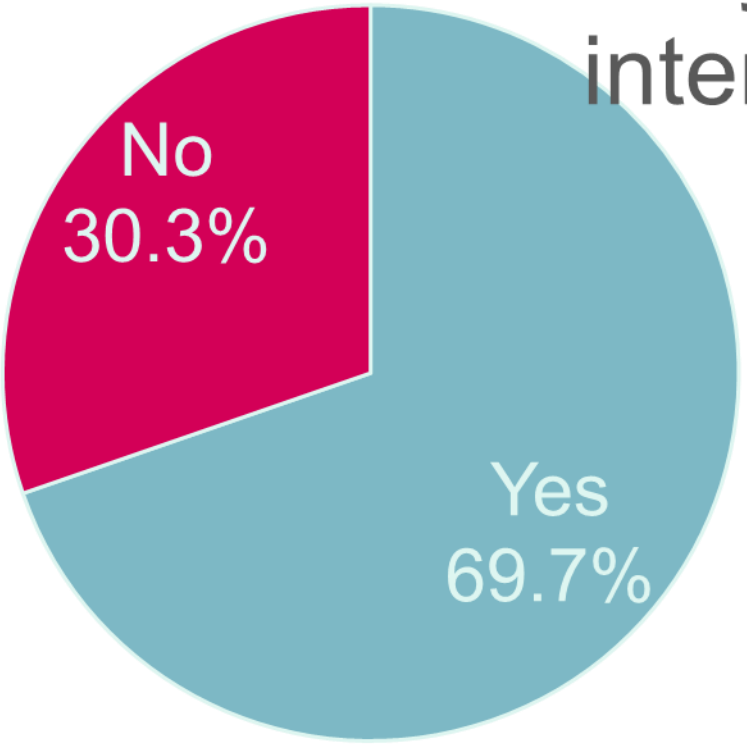
Country	N (%)	Country	N (%)
UK	111 (42)	The Netherlands	2 (0.8)
Ireland	91 (34.5)	Switzerland	1 (0.4)
Canada	31 (11.7)	Ethopia	1 (0.4)
Australia	11 (4.2)	South Africa	1 (0.4)
USA	5 (1.9)	Italy	1 (0.4)
Denmark	4 (1.5)	Prefer not to say	2 (0.8)
Norway	3 (1.1)		

Area of research	N (%)
Medical	122 (46.2)
Health services research	116 (43.9)
Allied health professionals	86 (32.6)
Nursing/midwifery	66 (25.0)
Psychology	64 (24.2)
Public health	63 (23.9)

Previous training/research in intervention fidelity	N (%)
Never received any formal or informal training	137 (51.7)
Informal self-directed research	83 (31.6)
Formal teaching (e.g. lectures, seminars)	24 (9.1)
Formal research (e.g. PhD, MSc)	20 (7.6)
Unsure	1 (0.4%)

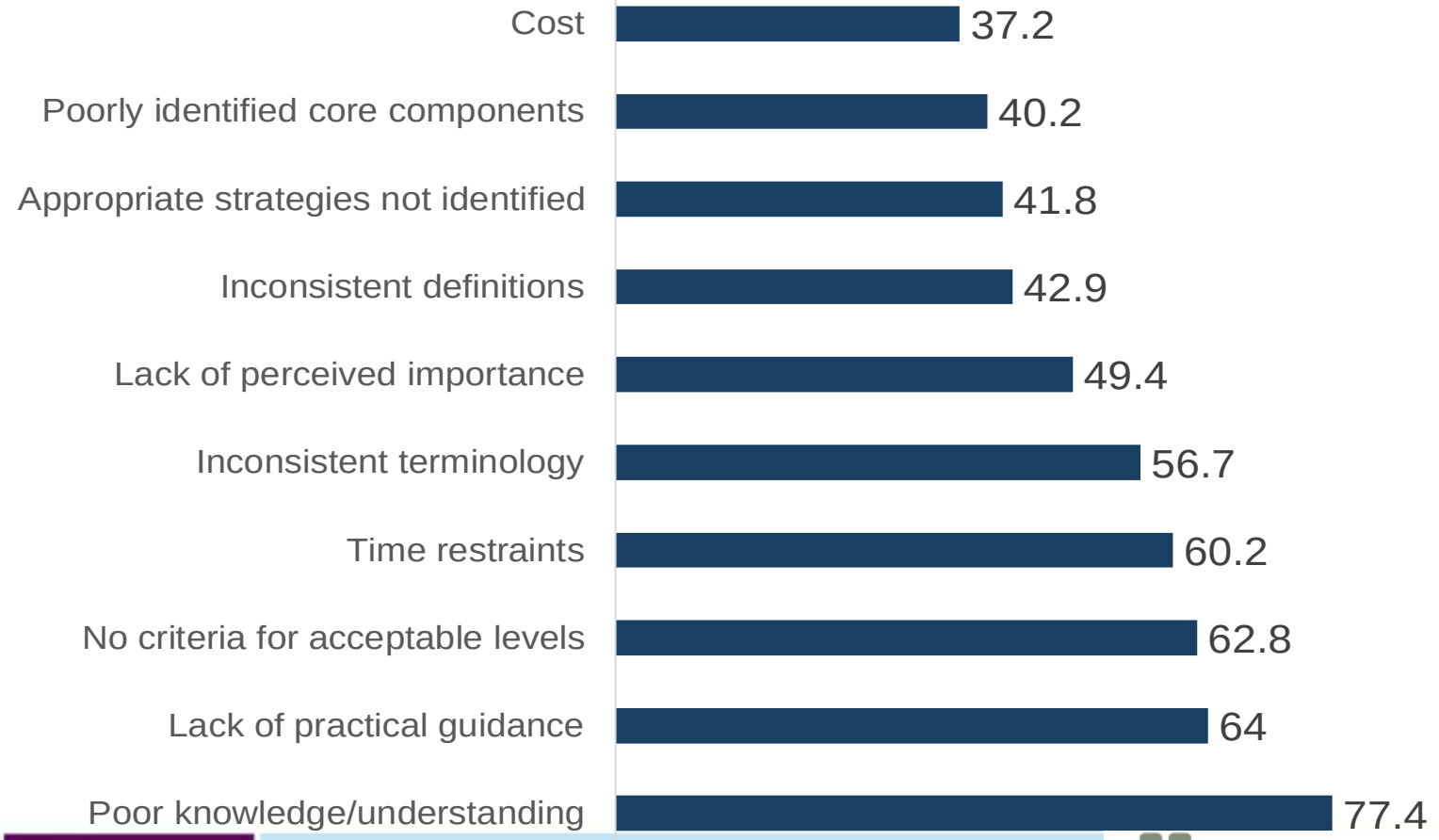
Results – knowledge

‘Are you **familiar** with intervention fidelity?’



Self-reported **understanding** of intervention fidelity was **5.84**±2.26
1(poor) to 10 (excellent)

What are the **barriers** to intervention fidelity?



What are the **facilitators** to intervention fidelity?

Results

Top 3 Barriers:

1. Time (n=71)
2. Knowledge/understanding (n=64)
3. Cost (n=59)

Top 3 Facilitators:

1. Available tools/checklists (n=61)
2. Good knowledge (n=54)
3. Funding (n=48)

Survey conclusions

- Good awareness of intervention fidelity and importance
- Lack of knowledge and understanding
- Practical issues – time, cost

- ➢ Need for better clarification of terminology and components
- ➢ Need for further training and education
- ➢ Need for practical guidance (i.e. feasibility)

Summary: So what's the problem?

- Behaviour change is a complex and important topic…
- Trials of behaviour change interventions limited by:
  - Focusing on outcome only with limited focus on process
    - » Limited understanding mechanisms of action
  - Poor focus on intervention fidelity/why or how interventions succeed or fail
    - » Limited interpretation of outcomes
    - » Limited ability to replicate successful interventions

1. Theory-based interventions and mechanisms of action

BMJ. 2008; 337: a1655. PMCID: PMC2769032
Published online 2008 Sep 29. doi: 10.1136/bmj.a1655

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

Peter Craig, programme manager,[✉1] Paul Dieppe, professor,[2] Sally Macintyre, director,[3] Susan Michie, professor,[4] Irwin Nazareth, director,[5] and Mark Petticrew, professor[6]

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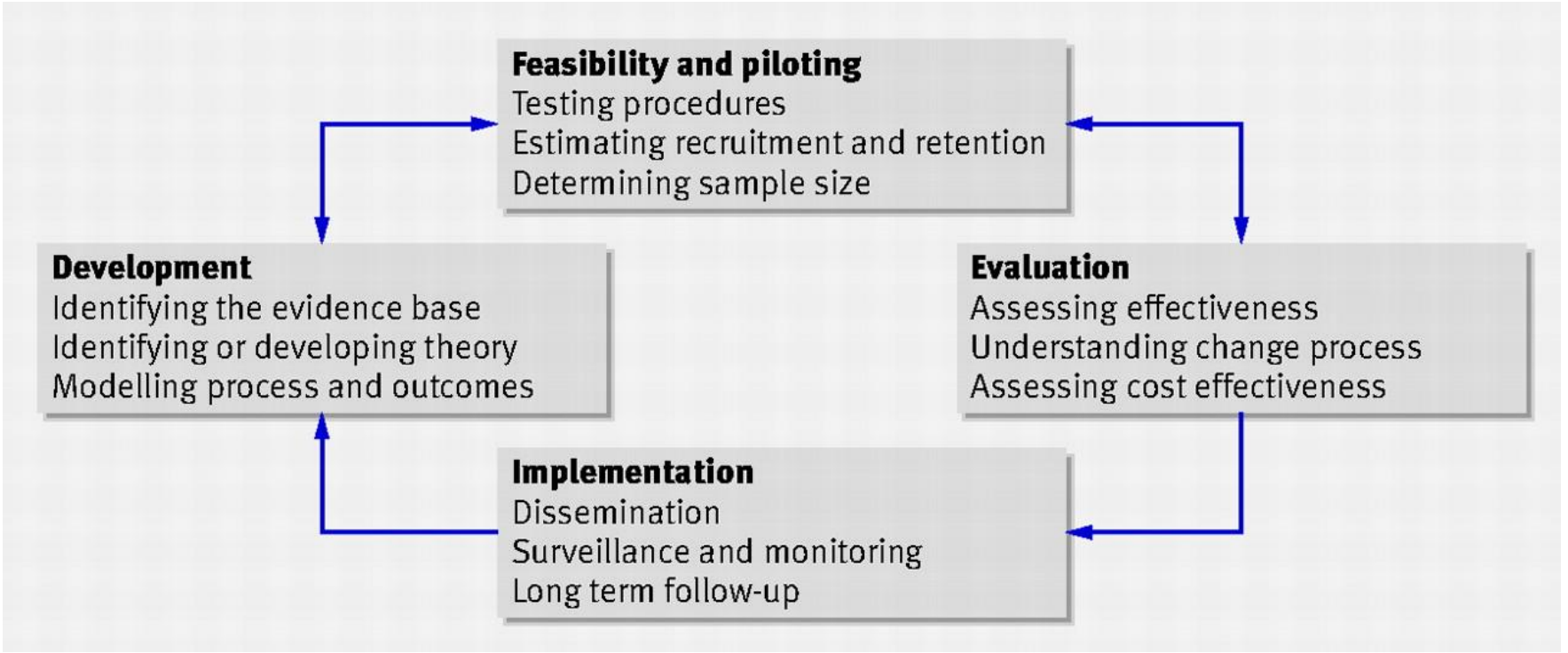
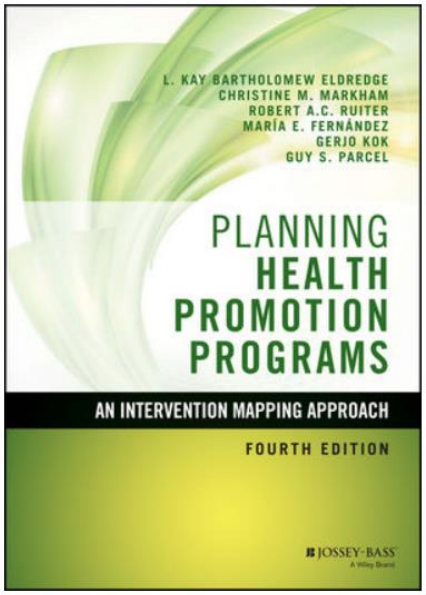




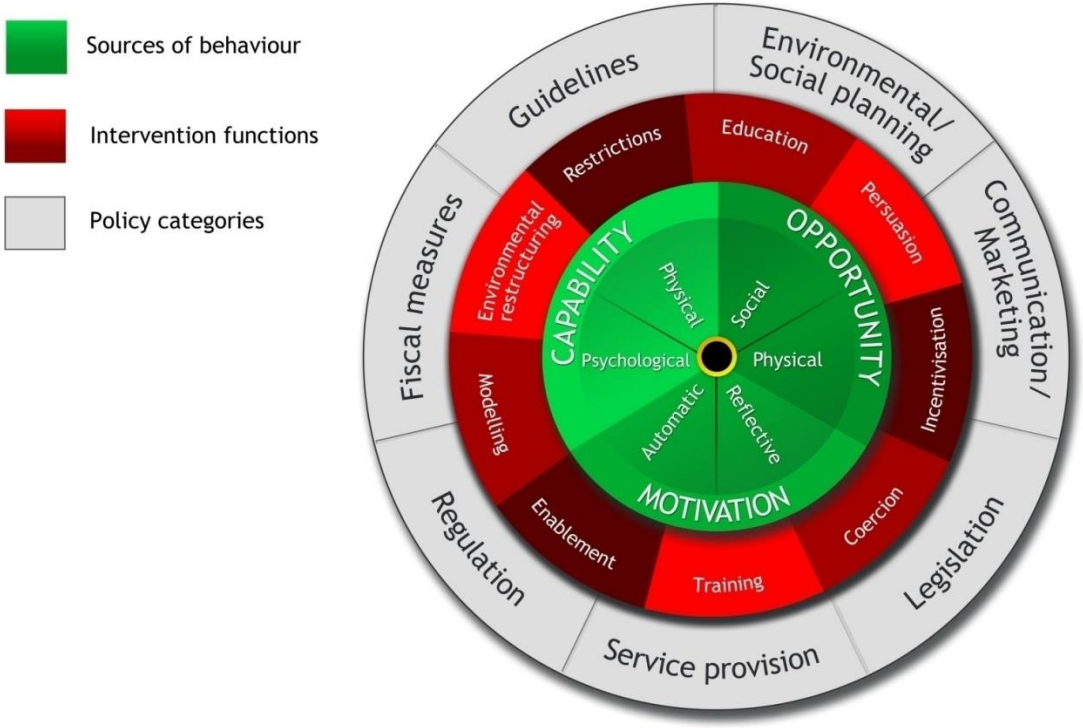
Evaluation

Implementation

Step 1: Logic Model of the Problem	• Establish and work with a planning group • Conduct a needs assessment to create a logic model of the problem • Describe the context for the intervention including the population, setting, and community • State program goals
Step 2: Program Outcomes and Objectives; Logic Model of Change	• State expected outcomes for behavior and environment • Specify performance objectives for behavioral and environmental outcomes • Select determinants for behavioral and environmental outcomes • Construct matrices of change objectives • Create a logic model of change
Step 3: Program Design	• Generate program themes, components, scope, and sequence • Choose theory- and evidence-based change methods • Select or design practical applications to deliver change methods
Step 4: Program Production	• Refine program structure and organization • Prepare plans for program materials • Draft messages, materials, and protocols • Pretest, refine, and produce materials
Step 5: Program Implementation Plan	• Identify potential program users (implementers, adopters, and maintainers) • State outcomes and performance objectives for program use • Construct matrices of change objectives for program use • Design implementation interventions
Step 6: Evaluation Plan	• Write effect and process evaluation questions • Develop indicators and measures for assessment • Specify the evaluation design • Complete the evaluation plan

The six steps of Intervention Mapping

The Behaviour Change Wheel



Research

Highly accessed | Open Access

The behaviour change wheel: A new method for characterising and designing behaviour change interventions

Susan Michie[1*], Maartje M van Stralen[2] and Robert West[2]

* Corresponding author: Susan Michie s.michie@ucl.ac.uk

For all author emails, please log on.

▸ Author Affiliations

Implementation Science 2011, **6**:42 doi:10.1186/1748-5908-6-42

Published: 23 April 2011

Abstract

Background

Improving the design and implementation of evidence-based practice depends on successful behaviour change interventions. This requires an appropriate method for characterising interventions and linking them to an analysis of the targeted behaviour. There exists a plethora of frameworks of behaviour change interventions, but it is not clear how well they serve this purpose. This paper evaluates these frameworks, and develops and evaluates a new framework aimed at overcoming their limitations.

Systematic Review:
19 frameworks
Combined into the BCW

Intervention Development Process

Stage 1: Understand the behaviour

1. Define the problem in behavioural terms
2. Select target behaviour
3. Specify the target behaviour
4. Identify what needs to change

Stage 2: Identify intervention options

Identify:

5. Intervention functions
6. Policy categories

Stage 3: Identify content and implementation options

Identify:

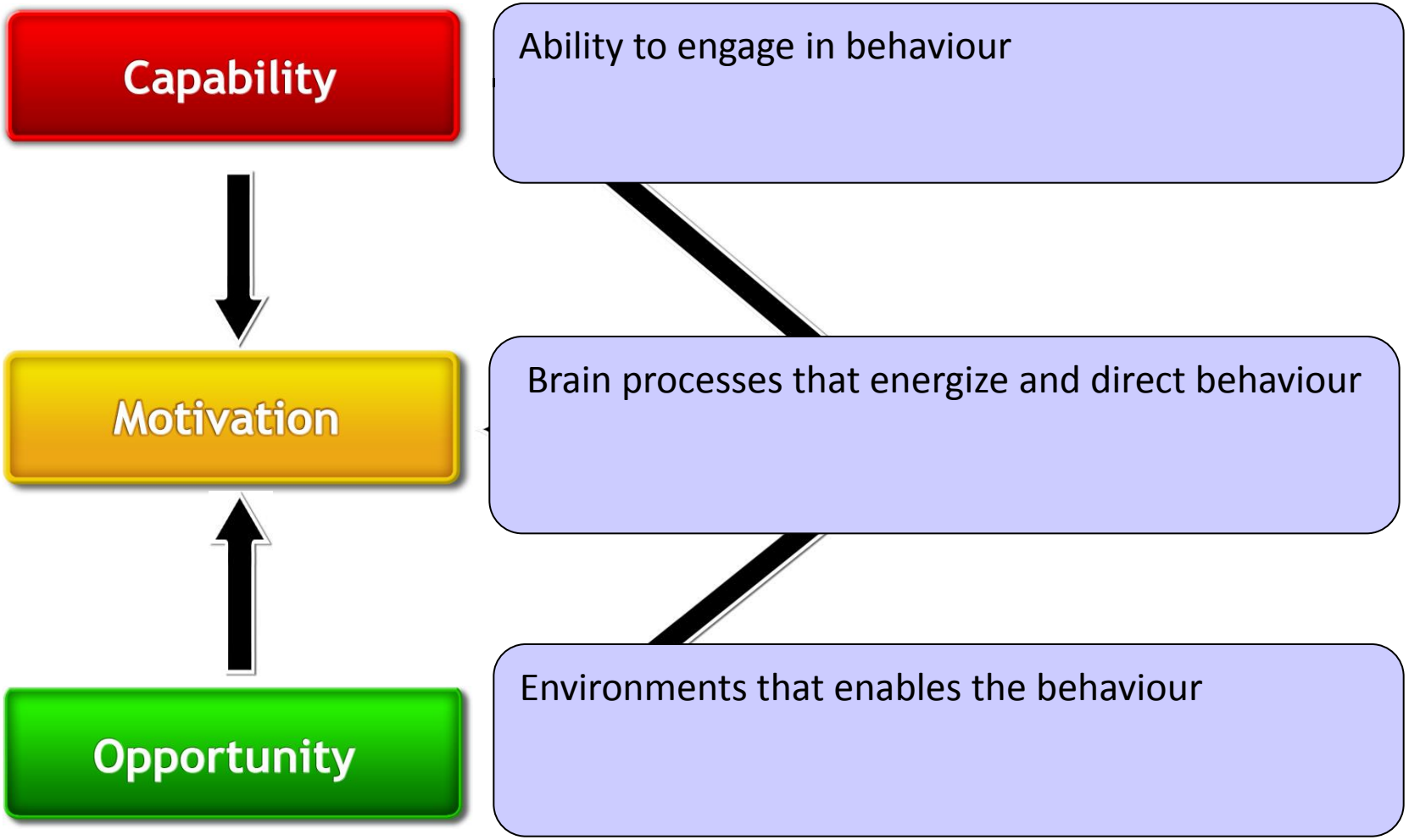
7. Behaviour change techniques
8. Mode of delivery

The Capability Opportunity Motivation – Behaviour (COM-B) Model

Changing any behaviour involves identifying what needs to change in terms of:
Capability
Motivation
Opportunity

HEALTH BEHAVIOUR CHANGE
RESEARCH GROUP

The COM-B Model



The COM-B Model

Ability to engage in behaviour

Physical capability (e.g. skills)

Physical skill, strength, or stamina

Psychological capability (e.g. knowledge)

Knowledge or psychological skills, strength or stamina to engage in the necessary mental processes

Brain processes that energize and direct behaviour:

Automatic (e.g. habits)

Automatic processes involving emotional reactions, wants and needs, impulses, and reflex responses

Reflective (e.g. goals)

Reflective processes involving plans (self-conscious intentions) and evaluations

Environments that enable the behaviour:

Social opportunity (e.g. social norms)

Interpersonal influences, social cues and cultural norms that influence the way we think about things

Physical opportunity (e.g. affordability)

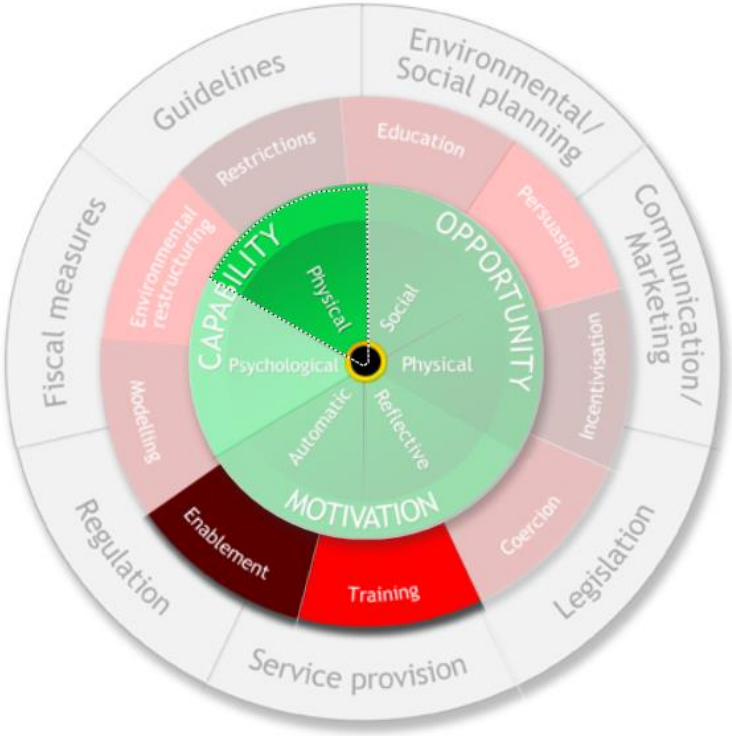
Opportunity afforded by the environment involving time, resources, locations, cues, physical 'affordance'

Sources of behaviour

Intervention functions

9 Intervention functions: Broad categories through which an intervention can change behaviour

Selecting Intervention Functions
Linking with COM-B components



http://www.behaviourchangewheel.com/

Enablement

HEALTH BEHAVIOUR CHANGE RESEARCH GROUP

Selecting Intervention Functions Linking with COM-B components

	Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental restructuring	Modelling	Enablement
C-Ph					■				■
C-Ps	■				■				■
O-Ph					■	■	■		■
O-So						■	■	■	■
M-A		■	■	■	■		■	■	■
M-R	■	■	■	■					

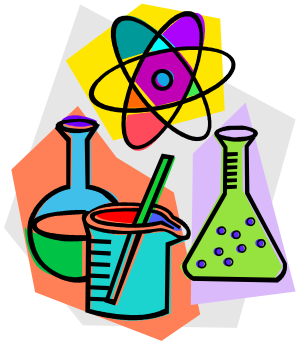
Selecting Intervention Functions
APEASE Criteria

BCW Intervention Functions	Affordability	Practicability	Effectiveness and cost effectiveness	Acceptability	Side effects/ safety	Equity	Decision Yes/No
Education	✓	✓	✓	✓	✓	✓	Yes
Persuasion	✓	✓	✓	✓	✓	✓	Yes
Incentivisation	✓	×	✓	×	×	✓	No
Coercion	✓	×	✓	×	×	✓	No
Training	✓	✓	✓	✓	✓	✓	Yes
Restriction	✓	×	✓	×	×	✓	No
Environmental Restructuring	×	×	✓	×	✓	✓	No
Modelling	✓	✓	✓	✓	✓	✓	Yes
Enablement	✓	✓	✓	✓	✓	✓	Yes

Identify Behaviour Change Techniques

Behaviour Change Technique (BCT)

"An observable, replicable, and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour"



→**Active ingredients of**

behaviour change interventions

(Abraham & Michie, 2008)

- Provides a common standardized vocabulary to define behaviour change intervention components

BCT Taxonomy (2013)

ann. behav. med. (2013) 46:81–95
DOI 10.1007/s12160-013-9486-6

ORIGINAL ARTICLE

The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions

Susan Michie, DPhil, CPsychol · Michelle Richardson, PhD · Marie Johnston, PhD, CPsychol · Charles Abraham, DPhil, CPsychol · Jill Francis, PhD, CPsychol · Wendy Hardeman, PhD · Martin P. Eccles, MD · James Cane, PhD · Caroline E. Wood, PhD

Published online: 20 March 2013

Consensus study with experts

Electronic Supplementary Materials Table 3. BCT Taxonomy (v1): 93 hierarchically-clustered techniques

Page	Grouping and BCTs	Page	Grouping and BCTs	Page	Grouping and BCTs
1	**1. Goals and planning**	8	**6. Comparison of behaviour**	16	**12. Antecedents**
	1.1. Goal setting (behavior) 1.2. Problem solving 1.3. Goal setting (outcome) 1.4. Action planning 1.5. Review behavior goal(s) 1.6. Discrepancy between current behavior and goal 1.7. Review outcome goal(s) 1.8. Behavioral contract 1.9. Commitment		6.1. Demonstration of the behavior 6.2. Social comparison 6.3. Information about others' approval		12.1. Restructuring the physical environment 12.2. Restructuring the social environment 12.3. Avoidance/reducing exposure to cues for the behavior 12.4. Distraction 12.5. Adding objects to the environment 12.6. Body changes
		9	**7. Associations**		
			7.1. Prompts/cues 7.2. Cue signalling reward 7.3. Reduce prompts/cues		

1.1	***Goal setting (behavior)***	Set or agree on a goal defined in terms of the behavior to be achieved *Note: only code goal-setting if there is sufficient evidence that goal set as part of intervention; if goal unspecified or a behavioral outcome, code **1.3, Goal setting (outcome)**; if the goal defines a specific context, frequency, duration or intensity for the behavior, <u>also</u> code **1.4, Action planning***	Agree on a daily walking goal (e.g. 3 miles) with the person and reach agreement about the goal Set the goal of eating 5 pieces of fruit per day as specified in public health guidelines

	3.3. Social support (emotional)		9.1. Credible source 9.2. Pros and cons 9.3. Comparative imagining of future outcomes		14.10. Remove punishment
6	**4. Shaping knowledge**			19	**15. Self-belief**
	4.1. Instruction on how to perform the behavior 4.2. Information about Antecedents 4.3. Re-attribution 4.4. Behavioral experiments	12	**10. Reward and threat**		15.1. Verbal persuasion about capability 15.2. Mental rehearsal of successful performance 15.3. Focus on past success 15.4. Self-talk
			10.1. Material incentive (behavior) 10.2. Material reward (behavior) 10.3. Non-specific reward 10.4. Social reward 10.5. Social incentive 10.6. Non-specific incentive 10.7. Self-incentive		
7	**5. Natural consequences**			19	**16. Covert learning**
	5.1. Information about health				16.1. Imaginary punishment

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Michie et al 2011

Identify Behaviour Change Techniques linked to intervention functions

Environmental restructuring	**Most frequently used BCTs:** • **Adding objects to the environment** • **Prompts/cues** • **Restructuring the physical environment** Less frequently used BCTs: • Cue signalling reward • Remove access to the reward • Remove aversive stimulus • Satiation • Exposure • Associative learning • Reduce prompt/cue • Restructuring the social environment

The CHARMS Study

Improving Sexual Assessment and Counselling in Cardiac Rehabilitation

HEALTH BEHAVIOUR CHANGE RESEARCH GROUP

Mc Sharry et al. Implementation Science (2016) 11:134
DOI 10.1186/s13012-016-0493-4

Implementation Science

METHODOLOGY Open Access

Implementing international sexual counselling guidelines in hospital cardiac rehabilitation: development of the CHARMS intervention using the Behaviour Change Wheel

J. Mc Sharry*, P. J. Murphy and M. Byrne

A Worked Example

http://charmsstudy.com/

This section is all to do with your leisure activity and how much exercise you take.

B1. In a **normal week,** how many times on average do you do the following kinds of exercise for **more than 20 minutes during your free time**?

(Please write the number of times **on each line**)

Times per Week

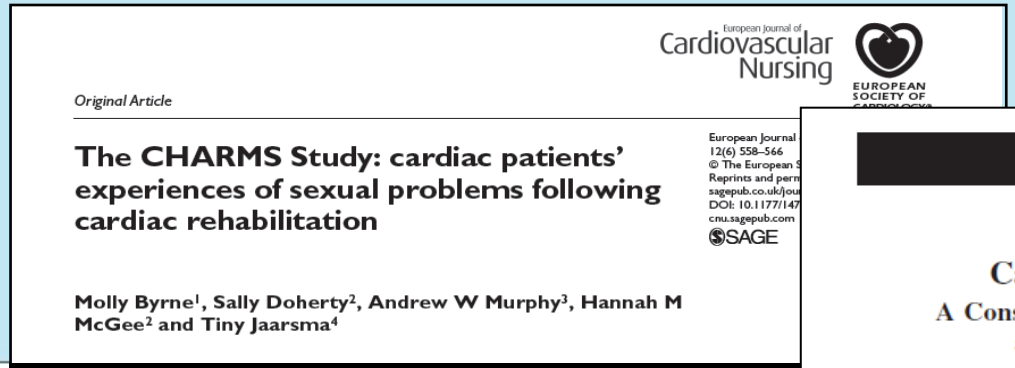
a) STRENUOUS EXERCISE (HEART BEATS RAPIDLY)
(e.g. running, jogging, hockey, football, soccer, squash, basketball, judo, roller skating, vigorous swimming, vigorous long distance cycling) _____

b) MODERATE EXERCISE (NOT EXHAUSTING)
(e.g. fast walking, tennis, badminton, easy swimming, easy cycling, volleyball, baseball, dancing, heavy gardening) _____

c) MILD EXERCISE (MINIMAL EFFORT)
(e.g. yoga, golf, easy walking, fishing, bowling, light gardening) 3

why don't you do some research about sex? Nobody mentions this . . .

B2. In a typical week, during your leisure time, how often do you engage in any regular activity, such as jogging or cycling, long enough to work up sweat?



European Journal of Cardiovascular Nursing

EUROPEAN SOCIETY OF CARDIOLOGY®

Original Article

The CHARMS Study: cardiac patients' experiences of sexual problems following cardiac rehabilitation

European Journal
12(6) 558–566
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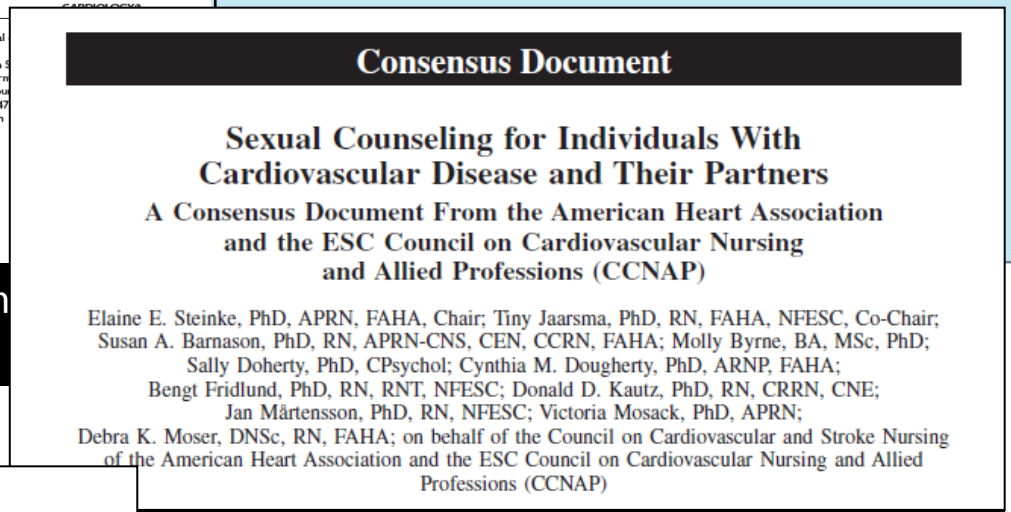
sagepub.co.uk/jou
DOI: 10.1177/147
cnu.sagepub.com
SAGE

Molly Byrne[1], Sally Doherty[2], Andrew W Murphy[3], Hannah M McGee[2] and Tiny Jaarsma[4]

Sexual problems twice as high in cardiac sam
general population



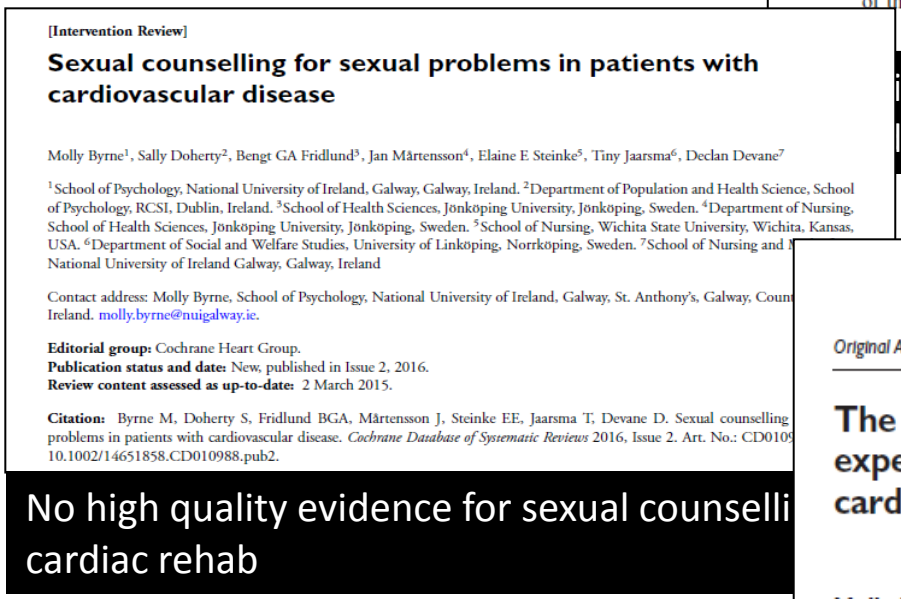
Consensus Document

Sexual Counseling for Individuals With Cardiovascular Disease and Their Partners

A Consensus Document From the American Heart Association and the ESC Council on Cardiovascular Nursing and Allied Professions (CCNAP)

Elaine E. Steinke, PhD, APRN, FAHA, Chair; Tiny Jaarsma, PhD, RN, FAHA, NFESC, Co-Chair; Susan A. Barnason, PhD, RN, APRN-CNS, CEN, CCRN, FAHA; Molly Byrne, BA, MSc, PhD; Sally Doherty, PhD, CPsychol; Cynthia M. Dougherty, PhD, ARNP, FAHA; Bengt Fridlund, PhD, RN, RNT, NFESC; Donald D. Kautz, PhD, RN, CRRN, CNE; Jan Mårtensson, PhD, RN, NFESC; Victoria Mosack, PhD, APRN; Debra K. Moser, DNSc, RN, FAHA; on behalf of the Council on Cardiovascular and Stroke Nursing of the American Heart Association and the ESC Council on Cardiovascular Nursing and Allied Professions (CCNAP)

ients should be offered sexual counselling as part
liac rehab



[Intervention Review]

Sexual counselling for sexual problems in patients with cardiovascular disease

Molly Byrne[1], Sally Doherty[2], Bengt GA Fridlund[3], Jan Mårtensson[4], Elaine E Steinke[5], Tiny Jaarsma[6], Declan Devane[7]

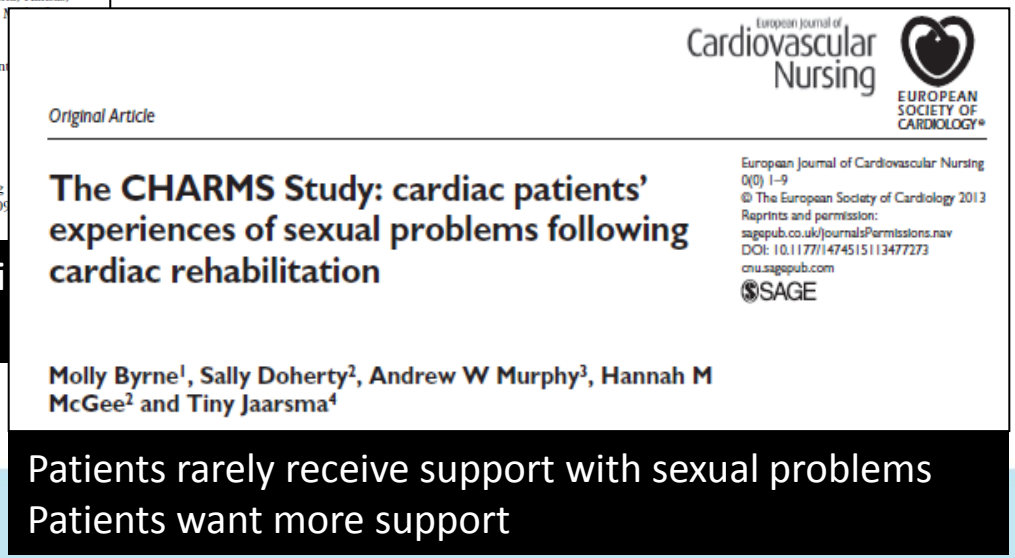
[1]School of Psychology, National University of Ireland, Galway, Galway, Ireland. [2]Department of Population and Health Science, School of Psychology, RCSI, Dublin, Ireland. [3]School of Health Sciences, Jönköping University, Jönköping, Sweden. [4]Department of Nursing, School of Health Sciences, Jönköping University, Jönköping, Sweden. [5]School of Nursing, Wichita State University, Wichita, Kansas, USA. [6]Department of Social and Welfare Studies, University of Linköping, Norrköping, Sweden. [7]School of Nursing and M
National University of Ireland Galway, Galway, Ireland

Contact address: Molly Byrne, School of Psychology, National University of Ireland, Galway, St. Anthony's, Galway, Count
Ireland. molly.byrne@nuigalway.ie.

Editorial group: Cochrane Heart Group.
Publication status and date: New, published in Issue 2, 2016.
Review content assessed as up-to-date: 2 March 2015.

Citation: Byrne M, Doherty S, Fridlund BGA, Mårtensson J, Steinke EE, Jaarsma T, Devane D. Sexual counselling
problems in patients with cardiovascular disease. *Cochrane Database of Systematic Reviews* 2016, Issue 2. Art. No.: CD010
10.1002/14651858.CD010988.pub2.

No high quality evidence for sexual counselli
cardiac rehab



European Journal of Cardiovascular Nursing

EUROPEAN SOCIETY OF CARDIOLOGY®

Original Article

The CHARMS Study: cardiac patients' experiences of sexual problems following cardiac rehabilitation

European Journal of Cardiovascular Nursing
0(0) 1–9
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DOI: 10.1177/1474515113477273
cnu.sagepub.com
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Molly Byrne[1], Sally Doherty[2], Andrew W Murphy[3], Hannah M McGee[2] and Tiny Jaarsma[4]

Patients rarely receive support with sexual problems
Patients want more support

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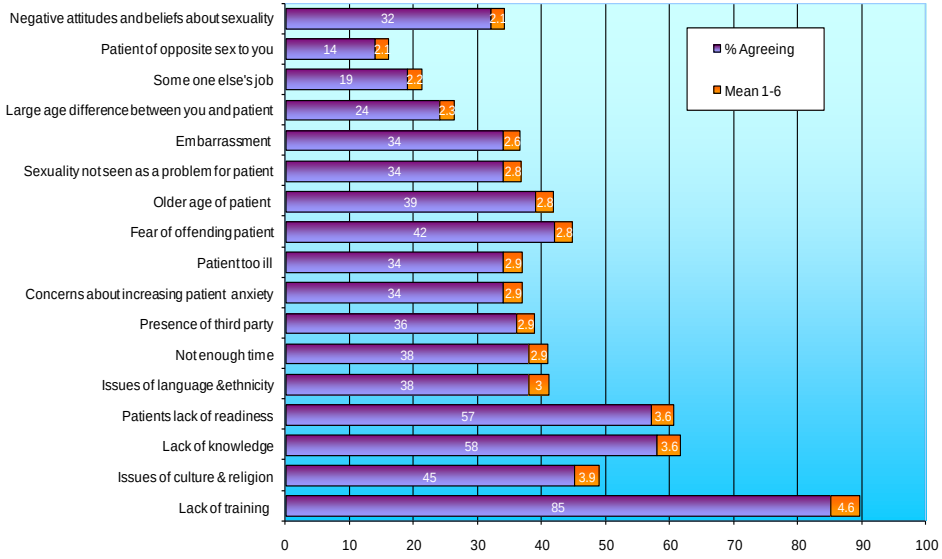
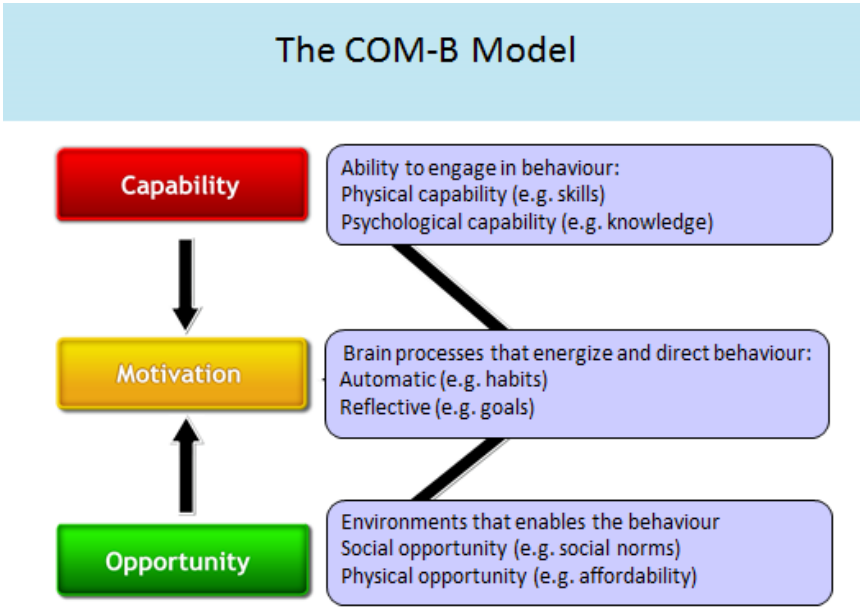
CHARMS Intervention: Specifying the Behaviour

Who needs to perform the behaviour?	Cardiac rehabilitation healthcare providers
What do they need to do differently to achieve the desired change ?	• Assess all patients for sexual concerns • Provide information and guidance about resuming sexual activity after a cardiac event • Assist patients with dealing with anxiety related to sexual concerns
When do they need to do it?	During phase III cardiac rehabilitation
Where do they need to do it?	Hospital cardiac rehabilitation centres in the Republic of Ireland
How often do they need to do it?	Once for every patient and respond appropriately to approaches from patients thereafter
With whom do they need to do it?	All patients attending phase III cardiac rehabilitation

CHARMS Intervention: Understanding the Behaviour





Doherty, S., Byrne, M., Murphy, A. W., & McGee, H. M. (2011). Cardiac rehabilitation staff views about discussing sexual issues with coronary heart disease patients: a national survey in Ireland. *European Journal of Cardiovascular Nursing, 10*(2), 101-107.

CHARMS Intervention: Understanding the Behaviour

Barriers identified from qualitative study (D'Eath et al., 2013)	**Barriers identified from national survey (Doherty et al., 2011)**	**COM-B Components**
• Lack of knowledge • Lack of information	• Lack of knowledge • Lack of training	CAPABILITY-PSYCHOLOGICAL
• Fear of offending • Perceived lack of patent awareness	• Patients lack of readiness	MOTIVATION-REFLECTIVE

Selecting Intervention Functions Linking with COM-B components

	Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental restructuring	Modelling	Enablement
C-Ph					■				■
C-Ps	■				■				■
O-Ph					■	■	■		■
O-So						■	■	■	■
M-A		■	■	■	■		■	■	■
M-R	■	■	■	■					

Selected intervention functions for CHARMS

Based on the APEASE criteria, the following intervention functions were selected:

Education

Persuasion

Training

Modelling

Enablement

The CHARMS Study

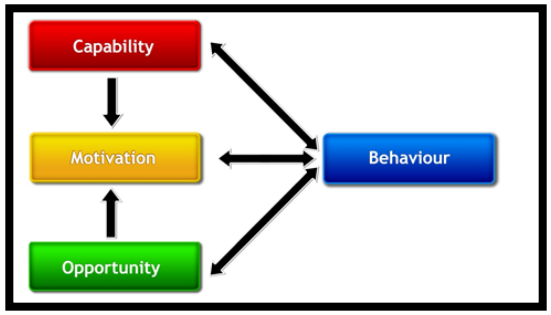
Improving Sexual Assessment and Counselling in Cardiac Rehabilitation

Selecting Intervention Functions
APEASE criteria

BCW Intervention Functions	Affordability	Practicability	Effectiveness and cost effectiveness	Acceptability	Side effects/ safety	Equity	Comments	Decision Yes/No
Education	✓	✓	✓	✓	✓	✓	Education was judged to meet all of the APEASE criteria: - Affordability: it is covered within budgetary allocations - Practicability: it can be delivered as a staff training module - Effectiveness: this is uncertain, but judged to be worth evaluating as part of the pilot study - Acceptability: CR staff would welcome relevant education and training (D'Eath et al) - Side-effects: risk of unwanted side-effects was judged to be minimal - Equity: no negative impact	

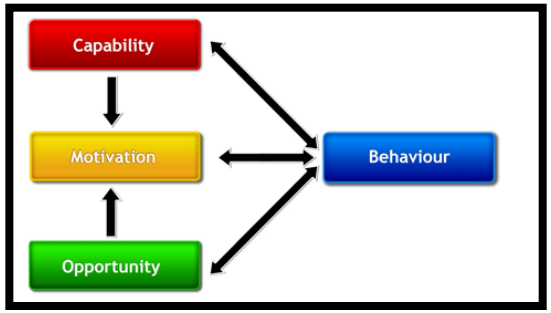
Linking it All Together:
Moving from COM-B to intervention function to BCTs to final intervention…

Barriers identified (Source)	COM-B Component	Selected Intervention Functions	Selected Behaviour Change Techniques	Translation of BCTs within the intervention
Lack of training (Doherty et al., 2011)				



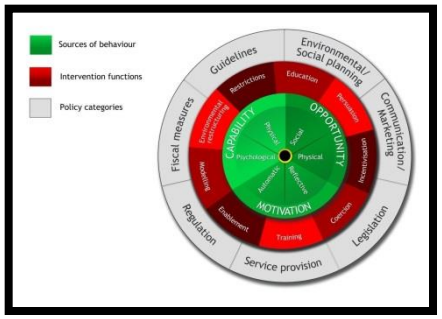
Linking it All Together:
Moving from COM-B to intervention function to BCTs to final intervention…

Barriers identified (Source)	COM-B Component	Selected Intervention Functions	Selected Behaviour Change Techniques	Translation of BCTs within the intervention
Lack of training (Doherty et al., 2011)	CAPABILITY-PSYCHOLOGICAL			



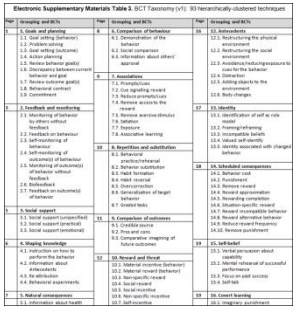
Linking it All Together:
Moving from COM-B to intervention function to BCTs to final intervention…

Barriers identified (Source)	COM-B Component	Selected Intervention Functions	Selected Behaviour Change Techniques	Translation of BCTs within the intervention
Lack of training (Doherty et al., 2011)	CAPABILITY-PSYCHOLOGICAL	Training		



Linking it All Together:
Moving from COM-B to intervention function to BCTs to final intervention…

Barriers identified (Source)	COM-B Component	Selected Intervention Functions	Selected Behaviour Change Techniques	Translation of BCTs within the intervention
Lack of training (Doherty et al., 2011)	CAPABILITY-PSYCHOLOGICAL	Training	4.1 Instruction on how to perform a behaviour	Provide manual and checklist of how to deliver group session Provide step by step guidance on how to address sexual concerns if raised
			6.1 Demonstration of behaviour	Show videos clips of good examples of HCPs interacting with patients who raise sexual concerns
			8.1 Behavioural practice/rehearsal	Role play exercises of interacting patients who raise sexual concerns



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Linking it All Together:
Moving from COM-B to intervention function to BCTs to final intervention…

Barriers identified (Source)	COM-B Component	Selected Intervention Functions	Selected Behaviour Change Techniques	Translation of BCTs within the intervention
Low confidence (among staff in the area of sexual counselling)	MOTIVATION-REFLECTIVE	Persuasion	15.1 Verbal persuasion about capability	The CHARMS Educator will provide verbal support and reassurance throughout the training session, telling the staff members that they can successfully provide sexual counselling to their patients.
		Modelling	6.1 Demonstration of the behaviour	Show video clips depicting a cardiac rehabilitation staff member providing sexual counselling in a confident, assured manner.

CHARMS intervention

1. The CHARMS Staff Intervention:

A two-hour training session for cardiac rehabilitation staff in sexual counselling skills

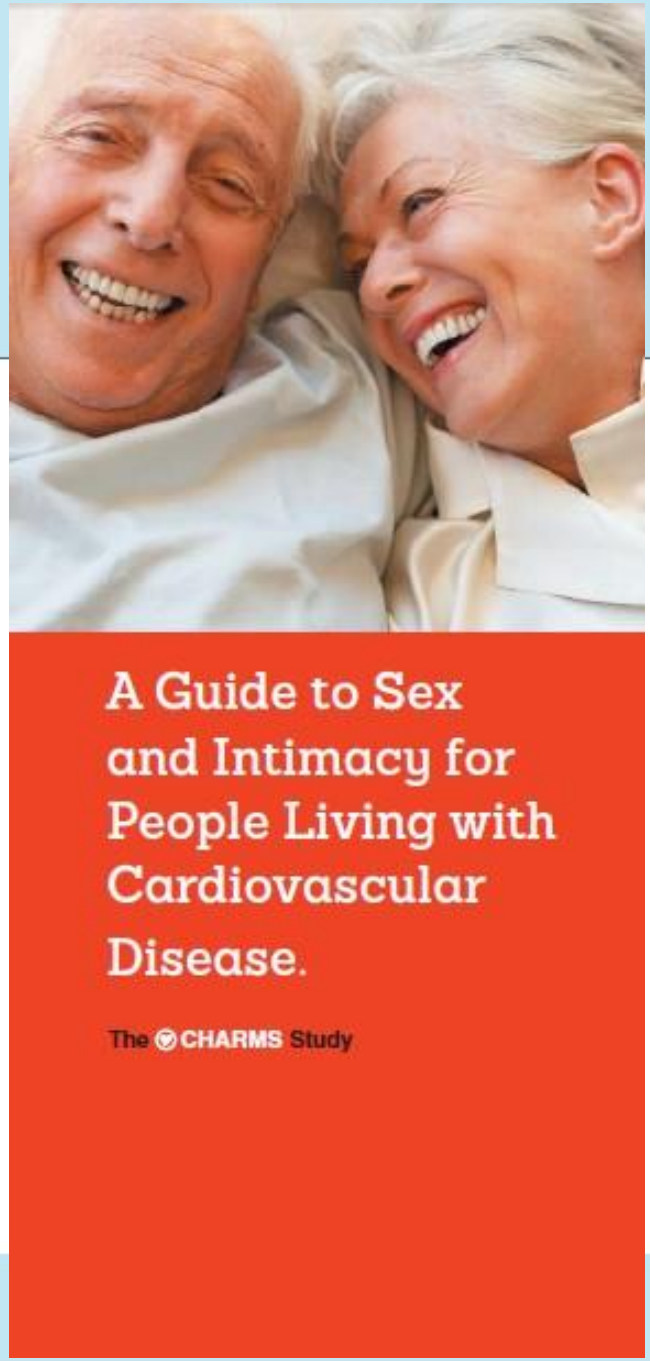
2. The CHARMS Patient Intervention:

A staff-led patient education and support session embedded within the cardiac rehabilitation programme

3. A Patient Information Booklet:

Developed by an expert panel for the American Heart Association and adapted for use in the CHARMS study

4. An Awareness Raising Poster



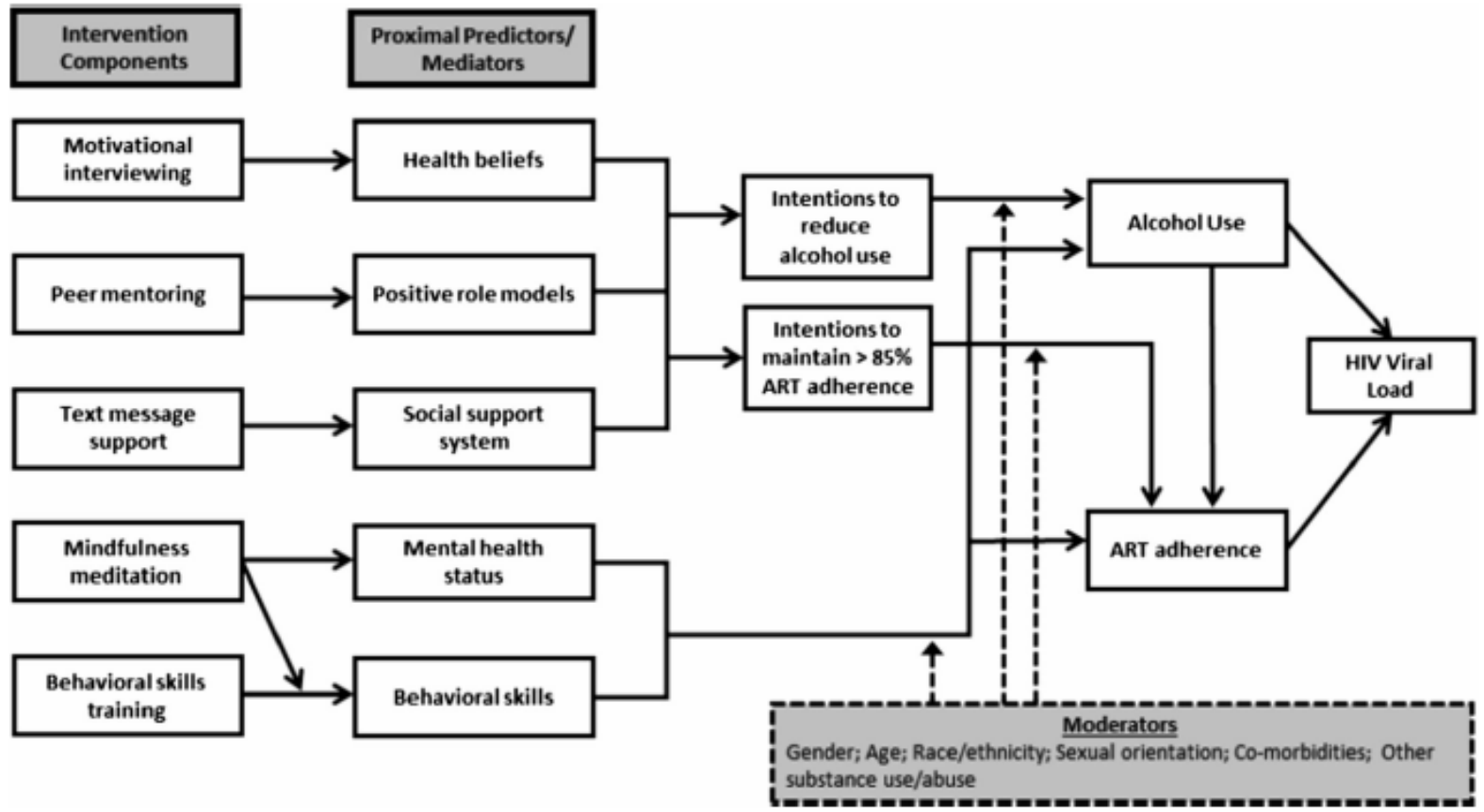


Fig. 1 Conceptual model of alcohol use and ART adherence among persons living with HIV/AIDS

Collins, L. M., Kugler, K. C., & Gwadz, M. V. (2016). Optimization of multicomponent behavioral and biobehavioral interventions for the prevention and treatment of HIV/AIDS. *AIDS and Behavior*, *20*(1), 197-214.

Hurley, D. A., Hall, A. M., Currie-Murphy, L., Pincus, T., Kamper, S., Maher, C., ... & Segurado, R. (2016). Theory-driven group-based complex intervention to support self-management of osteoarthritis and low back pain in primary care physiotherapy: protocol for a cluster randomised controlled feasibility trial (SOLAS). BMJ open, 6(1), e010728.

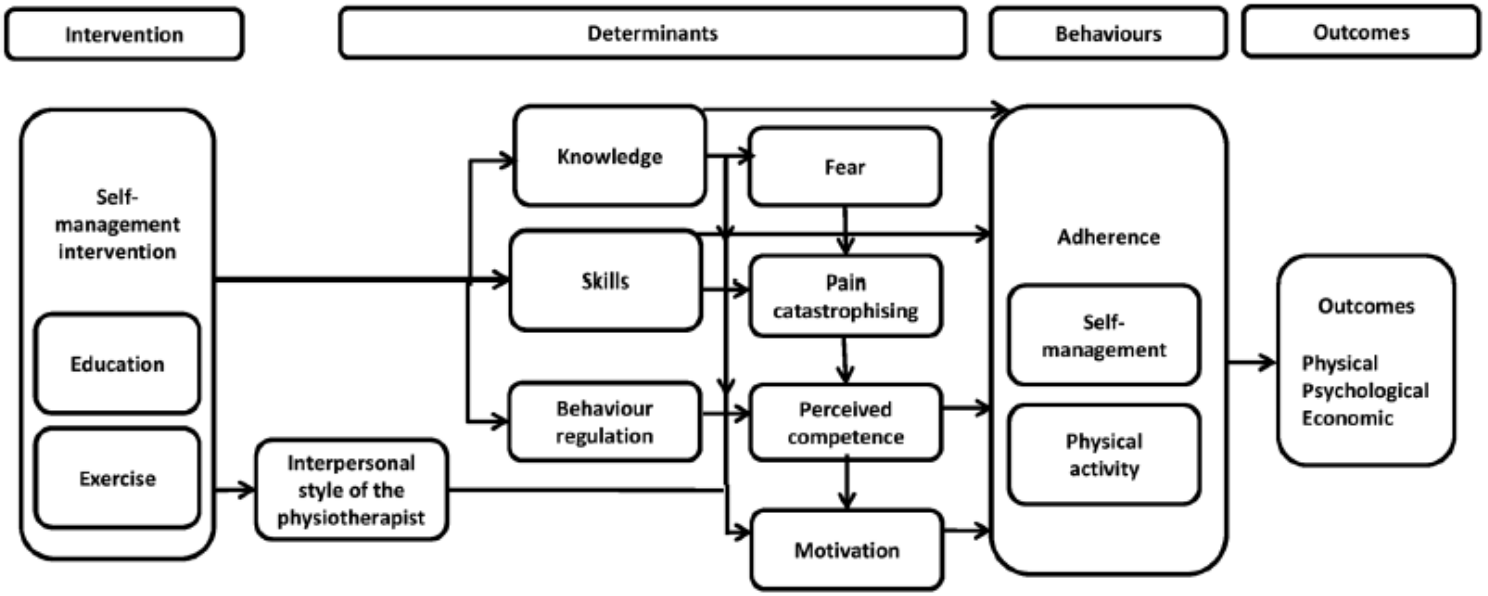
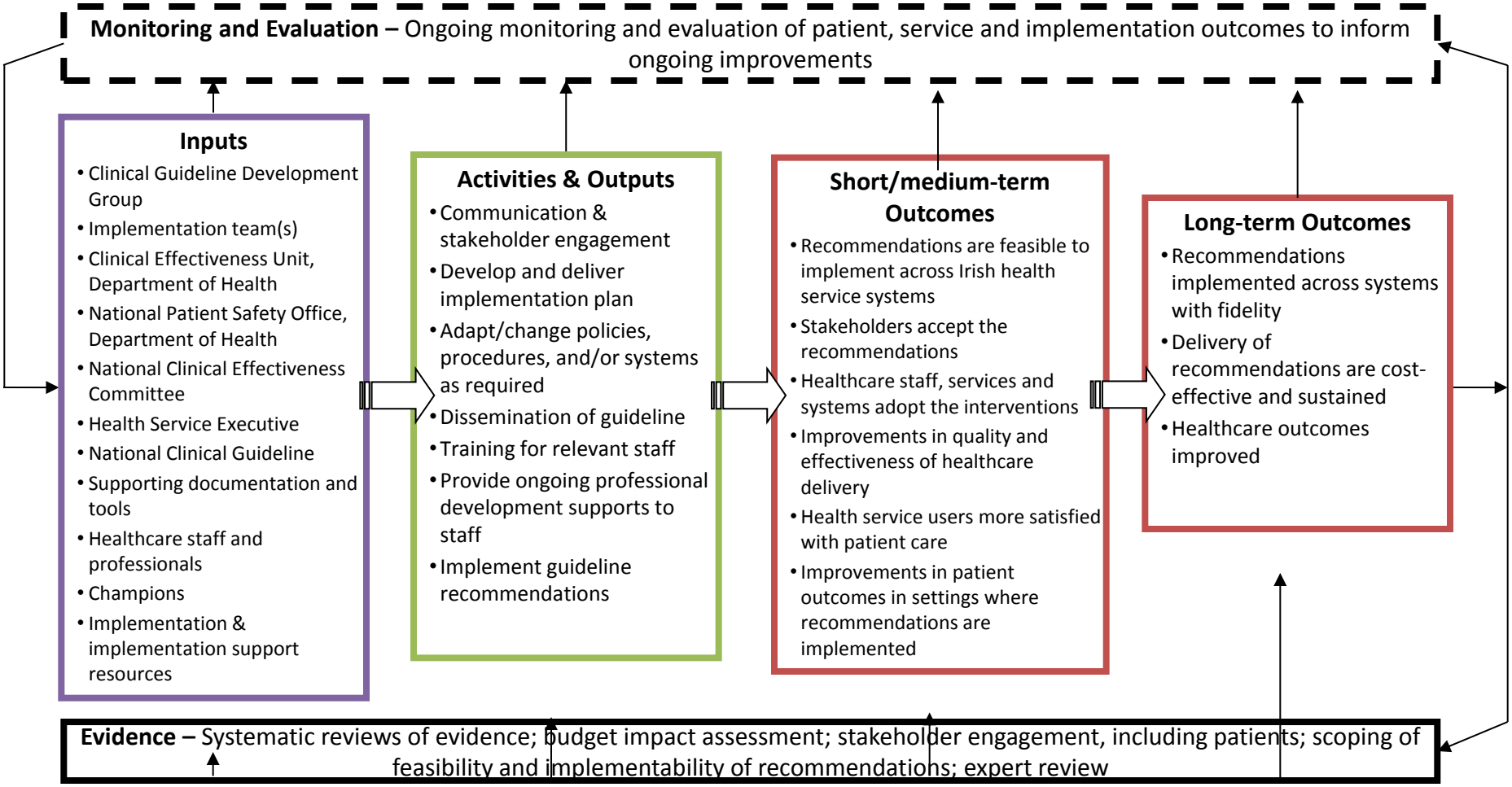
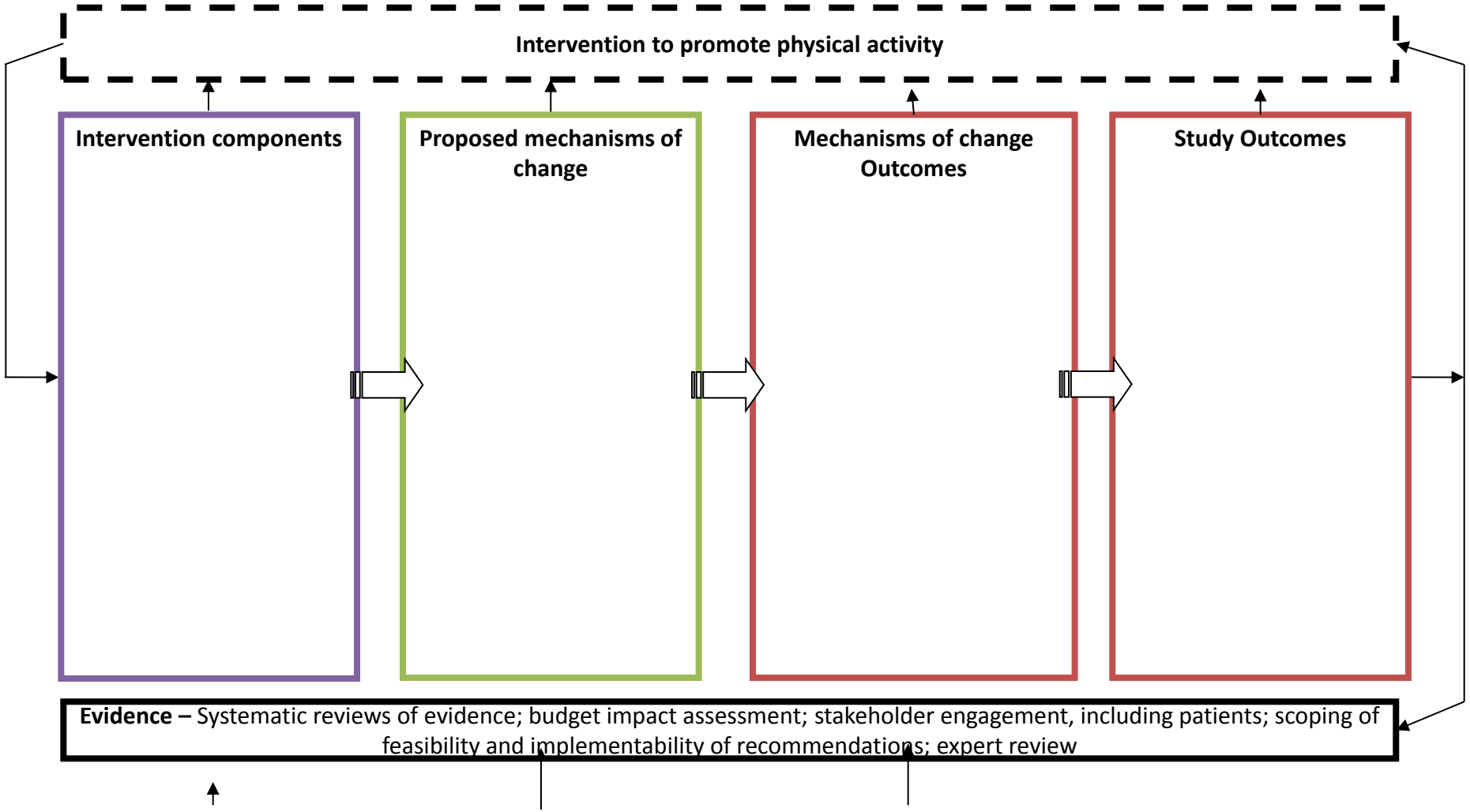


Figure 1 Process map of behaviour change in SOLAS intervention.



This draft template was shared at the 2-day Training in Implementation Science on the 17th and 18th May 2017 organised by the Clinical Effectiveness Unit in the Department of Health


Intervention to promote physical activity
Intervention components
Proposed mechanisms of change
Mechanisms of change
Outcomes
Study Outcomes
Evidence – Systematic reviews of evidence; budget impact assessment; stakeholder engagement, including patients; scoping of feasibility and implementability of recommendations; expert review

Activity 1

Break

2. Enhancing and assessing intervention fidelity

Intervention fidelity

- Intervention fidelity – 'extent to which intervention is implemented as intended by developers' (Carroll et al 2007)

- 'Methodological strategies to **monitor (assess)** and **enhance (improve)** reliability and validity of behavioural interventions' (Bellg et al 2004)

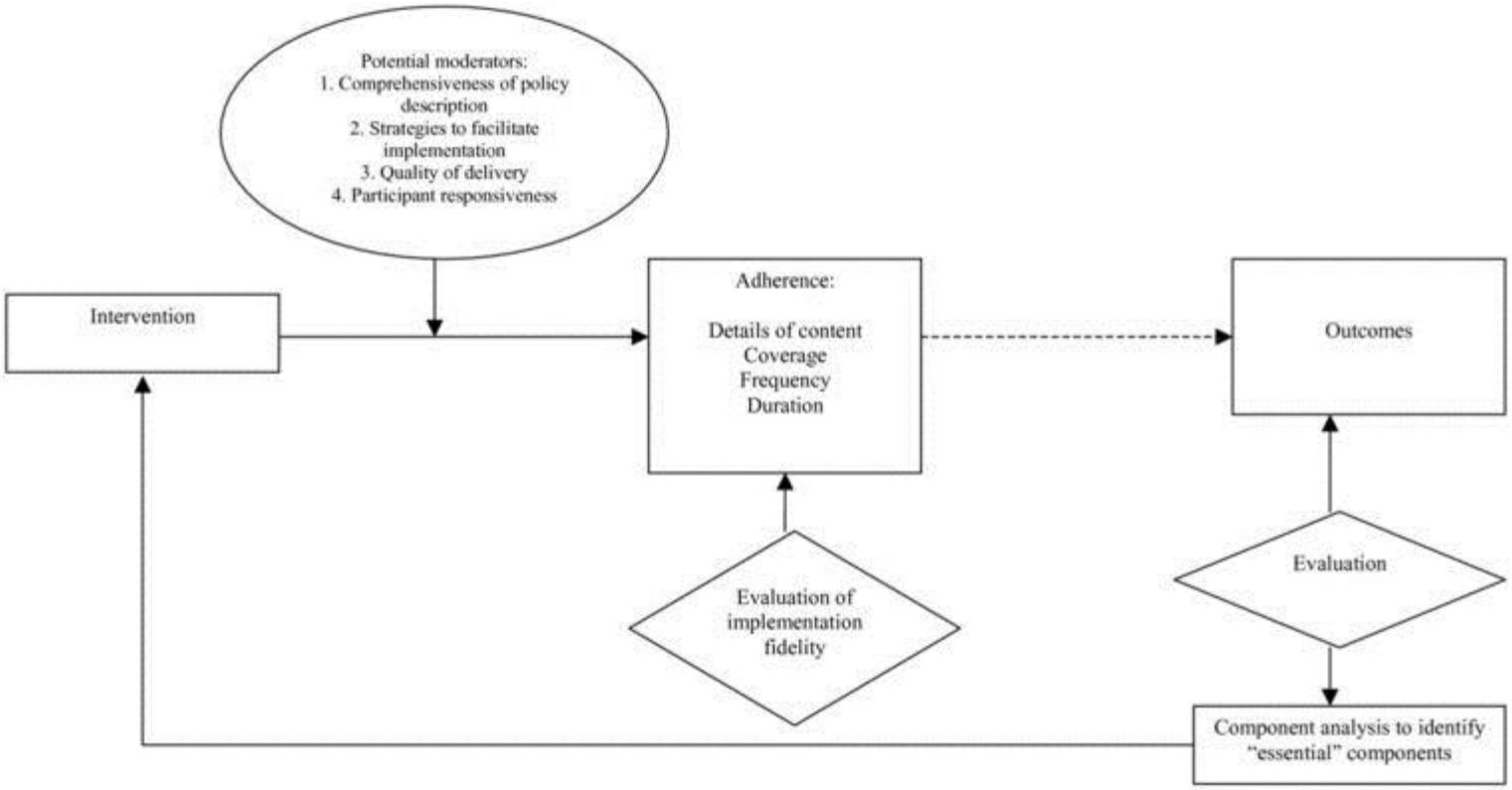
What do we know?

- Fidelity is **complex** – important to address systematically, comprehensively
- Good theoretical papers and frameworks exist
- 73.6% of researchers, triallists and healthcare professionals - never used specific fidelity framework/tool (McGee et al. under review)

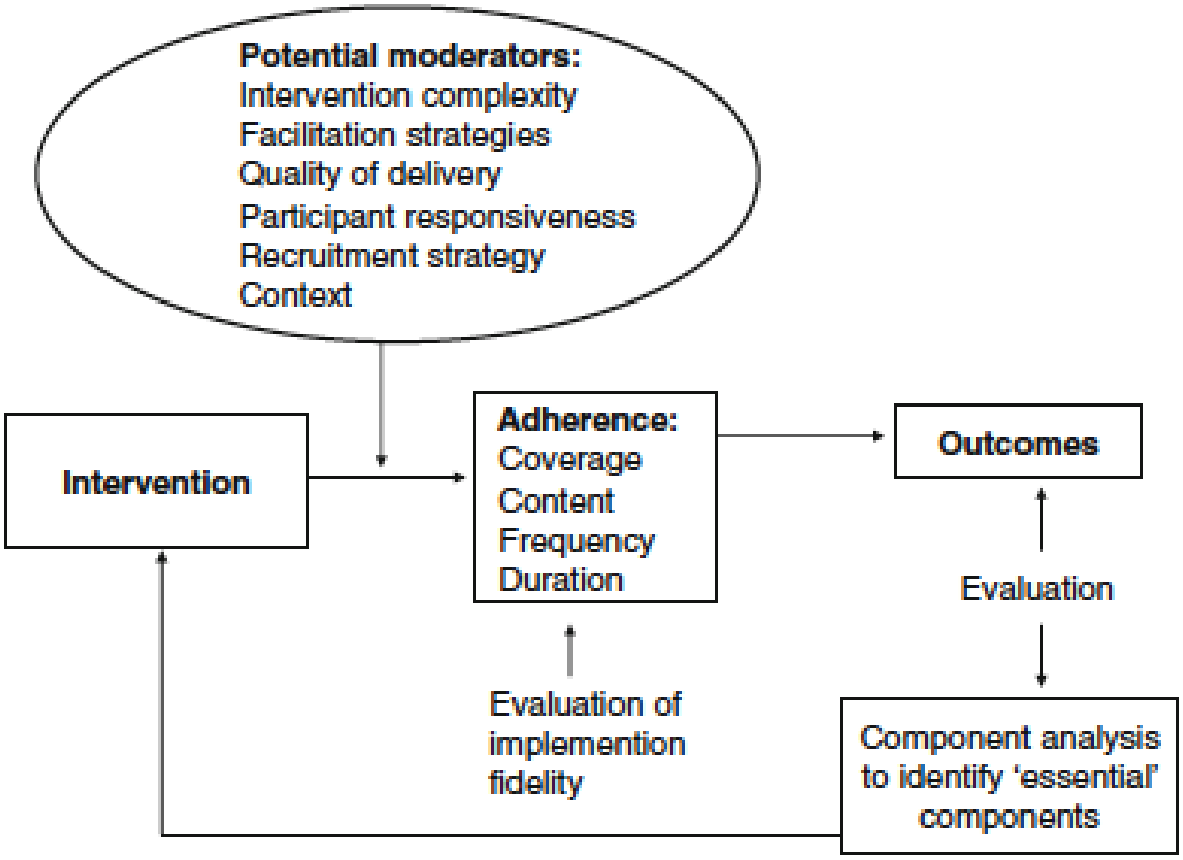
Survey findings

Fidelity frameworks/tools used if used	N (68 total possible) (%)
2011 Updated NIHBCC Treatment Fidelity Framework (Borrelli 2011)	26 (10.1)
Conceptual Framework for Implementation Fidelity (Carroll et al 2007)	26 (10.1)
2004 NIHBCC Treatment Fidelity Framework (Borrelli et al 2005)	19 (7.4)
Unsure/Don't know	6 (2.3)
Comprehensive Intervention Fidelity Guide (Gearing et al 2011)	5 (1.9)
Other	15 (5.8)
Medical Research Council Guidance on Process Evaluation of Complex Interventions	3 (1.2)
TIDieR checklist	2 (0.8)
Developed specifically for study	1 (0.4)
Multiple 'ad hoc' publications consulted	1 (0.4)
RE-AIM framework	1 (0.4)
Framework/Taxonomy of Implementation	1 (0.4)
Precede-Proceed	1 (0.4)
Conceptual Framework of Implementability	1 (0.4)
Process Evaluation 'How-to' Guide	1 (0.4)
BCT Taxonomy v1	1 (0.4)
Karas and Plankis 2016	1 (0.4)
Durlak and DuPre 2008	1 (0.4)
SPIRIT Intervention Fidelity Assessment Tool	1 (0.4)

Conceptual Framework for Implementation Fidelity (CFIF) (Carroll et al 2007)



Modified CFIF (Hasson et al. 2010)

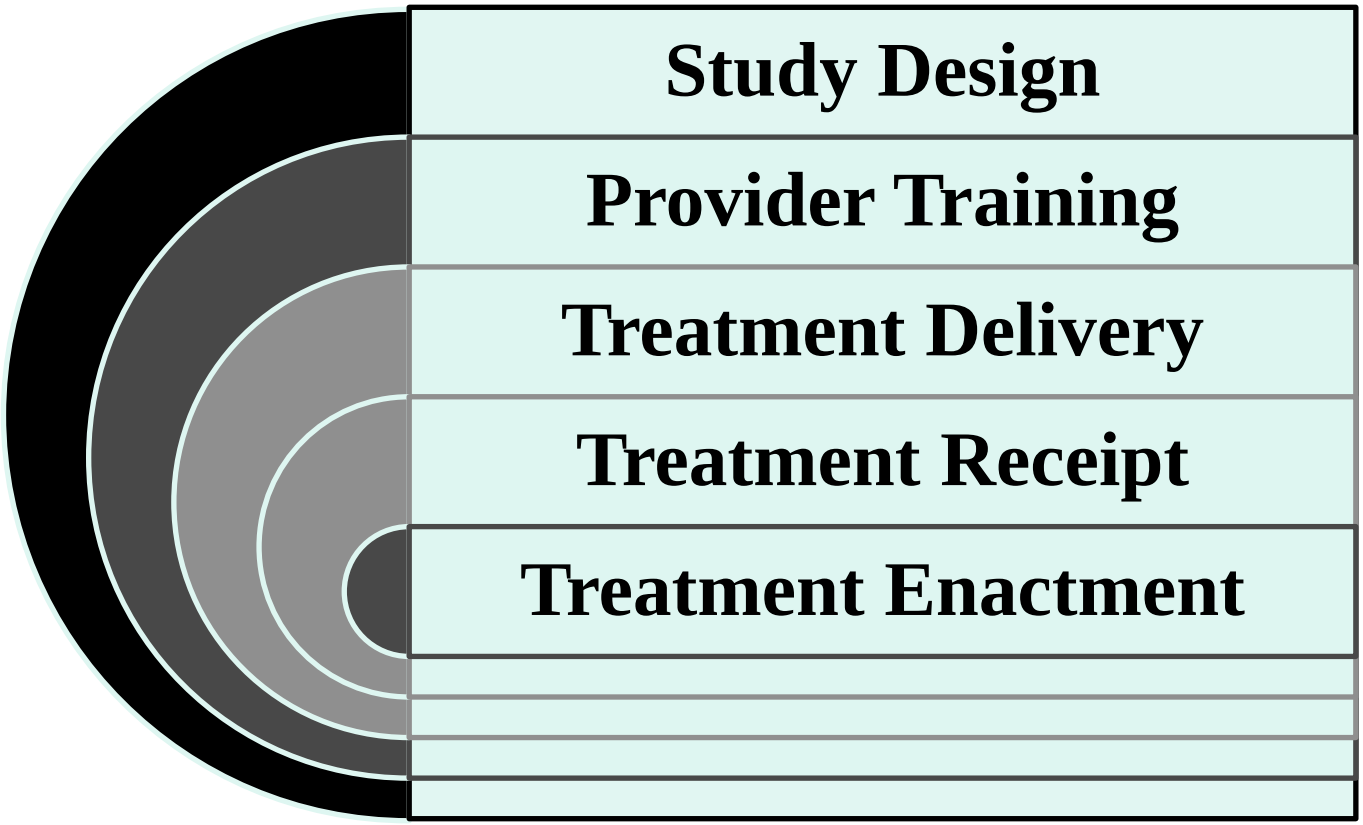


Comprehensive Intervention Fidelity Guide (Gearing et al 2011)

Assessment of major fidelity components.

Intervention design	Intervention training	Monitoring intervention delivery	Monitoring intervention receipt
Measurement 1) Types of instruments A. Planned what instrument to use 2) Measurement raters A. Planned type(s) of evaluators B. Established standard for inter-rater reliability 3) Method of observation A. Selected method(s) of observation. 4) Psychometric properties A. Validity B. Reliability C. Confirmed in previous literature or pilot study 5) Sampling for consistency A. Planned protocol for sampling	Measurement 1) Types of instruments A. Use pre- and post-test knowledge measures 2) Measurement raters N/A 3) Method of observation A. Video B. Audio C. Observation D. Self-report 4) Psychometric properties A. Validity B. Reliability 5) Sampling for consistency N/A 6) Attendance for full training 7) Understanding components of intervention measure 8) Skill acquisition measure 9) Belief in intervention effectiveness	Measurement 1) Types of instruments A. Checklists A. Likert scales B. Frequency C. Occurrence/non-occurrence D. Dose delivered E. Case formulations 2) Measurement raters A. Internal evaluators I. Interventionist II. Study participant III. Supervisors IV. Others B. External evaluator I. Known II. Blind C. Inter-rater reliability 3) Method of observation A. Video B. Audio C. Observation D. Self-report 4) Psychometric properties A. Validity B. Reliability 5) Sampling for consistency A. Randomly selected versus predetermined selection I. Across participant II. Across time III. Across provider B. Unit of measure (whole sessions vs. parts of sessions) 6) Methods to develop criteria should be	Measurement 1) Types of instruments A. Checklists B. Likert scales C. Frequency D. Occurrence/non-occurrence E. Use pre- and post-test knowledge measures F. Specify measures I. Self-report on understanding II. Self-report on behaviors III. Chart review on client behaviors IV. Client satisfaction measures 2) Measurement raters A. Internal evaluators I. Interventionist, II. Participants III. Supervisors, IV. Others B. External evaluator I. Known, II. Blind C. Inter-rater reliability 3) Method of observation A. Video B. Audio C. Observation D. Self-report 4) Psychometric properties A. Validity B. Reliability 5) Sampling for consistency A. Randomly selected versus predetermined selection I. Across participant II. Across time III. Across provider 6) Unit of measure (whole sessions vs.

National Institutes of Health Behaviour Change Consortium (NIHBCC) Fidelity Framework (Bellg et al 2004; Borrelli et al 2005/2011)



Rate: Present, Absent but should be present, and Not Applicable. If present, describe the strategy used for that component		
Design	1) Provided information about treatment dose in the intervention condition:	
	• Length of contact (minutes)	
	• Number of c	
	• Content of t	
	• Duration of	
	2) Provided informa	
	• Length of co	
	• Number of c	
	• Content of t	
	• Duration of	
	• Method to e	
	• Method to e	
	3) Specification of p	
	4) Theoretical mod	
	• The active in	
	• Use of exper protocol refl	
	• Plan to ensu constructs/n	
	5) Potential confou	
		7) If more than one intervention is described, all described equally well*
	Training Providers	1) Description of how providers will be trained (manual of training procedures)
		2) Standardization of provider training (especially if multiple waves of training are needed for multiple groups of providers)
		3) Assessment of provider skill acquisition
		4) Assessment and monitoring of provider skill maintenance over time
		5) Characteristics being sought in a treatment provider are articulated a priori. Characteristics that should be avoided in a treatment provider are articulated a priori*
		6) At the hiring stage, assessment of whether or not there is a good fit between the provider and the intervention (e.g., ensure that providers find the intervention acceptable, credible and potentially efficacious*
		7) There is a training plan that takes into account trainees' different education and experience and learning styles*
	Delivery of Treatment	1) Method to ensure that the content of the intervention is delivered as specified
		2) Method to ensure that the dose of the intervention is delivered as specified
		3) Mechanism to assess if the provider actually adhered to the intervention plan or in the case of computer delivered interventions, method to assess participants' contact with the information
		4) Assessment of nonspecific treatment effects
		5) Used treatment manual
		6) There is a plan for the assessment of whether or not the active

Borrelli et al 2005, Borrelli et al 2011

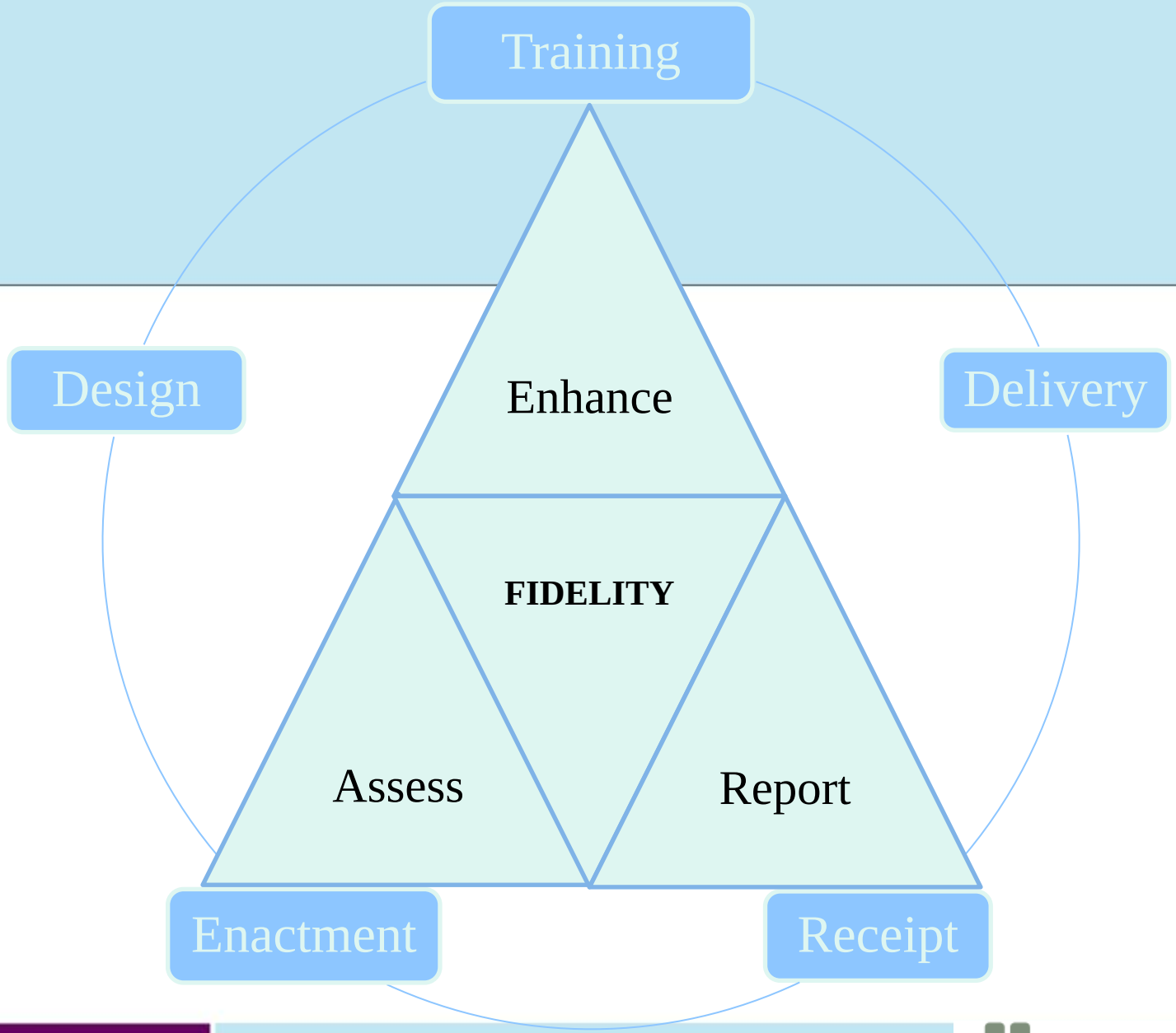
Framework comparisons

- Carroll et al 2007/Hasson et al 2010 (CFIF):
  - Led by psychology researchers, no specific setting
  - Conceptual level
- Gearing et al 2011 (CIFG):
  - Community-based psychological, social, and behavioural intervention research
  - Less utilised
  - Structured, comprehensive
- Bellg/Borrelli et al 2004/2005/2011 (NIHBCC):
  - Health behaviour change interventions
  - Validity and reliability tested
  - Structured, comprehensive

Framework similarities

- Consider fidelity as broader than delivery
  - Fidelity to intervention design/theory
  - Importance of how providers are trained
  - Involvement of participants

- Strategies to enhance (i.e. improve), assess (monitor) and report fidelity


Training
Design
Delivery
Enhance
FIDELITY
Assess
Report
Enactment
Receipt

What do these fidelity strategies look like?

Systematic reviews of fidelity strategies

British Journal of Health Psychology (2017)

The British Psychological Society

www.wileyonlinelibrary.com

Measures of fidelity of delivery of, and engagement

Rixon *et al. BMC Health Services Research* (2016) 16:663
DOI 10.1186/s12913-016-1904-6

BMC Health Services Research

RESEARCH ARTICLE Open Access

CrossMark

Methods used to address fidelity of receipt in health intervention research: a citation analysis and systematic review

Lorna Rixon[1*], Justine Baron[2], Nadine McGale[1], Fabiana Lorencatto[1], Jill Francis[1] and Ann

HEALTH BEHAVIOUR CHANGE RESEARCH GROUP

Types of strategies used

Type of measures used	Observational measures (n = 17; 38.6%):
	Video (n = 2; 4.55%)[27,51]
	Audio (n = 13; 29.5%)[7,19,21,22,38,40,45,48,55,57,58,63,64]
	Non-specific (n = 2; 4.55%)[1,34]
	Self-report measures (n = 15; 34%):
	Provider (hand) (n = 7; 15.9%)[6,10,14,16,41,42,59]
	Provider (computer) (n = 3; 6.8%)[24,23,36]
	Participant (hand) (n = 2; 4.6%)[28,11]
	Participant (computer) (n = 1; 2.3%)[49]
	Non-specific (computer) (n = 2; 4.6%)[62,66]
	Multiple measures (n = 11; 25%)
	Provider and participant self-report (n = 4; 9%)[2,30,35,50]
	Audio and provider self-report (n = 3; 6.8%)[20,26,39]
	Video + provider self-report (n = 1; 2.3%)[5]
	Observation and exercise log (participant) (n = 1; 2.3%)[31]
	Direct observation and rating (n = 1; 2.3%)[29]
	Participant self-report and patient files (n = 1; 2.3%)[60]
	Other measures (n = 1; 2.3%)
	Quantitative rated interviews with providers (n = 1; 2.3%)[33]

Assessing fidelity of delivery (Walton et al 2017)

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Survey findings – assessment strategies identified

Mr. Daragh McGee[1], Dr. Fabiana Lorencatto[1], Dr. Karen Matvienko Sikar[1], Dr. Elaine Toomey[1]
[1]National University of Ireland Galway, [2]University College London, [3]University College Cork

Health Research Board TMRN Trials Methodology Research Network

FIDELITY STRATEGIES	N (%)
Provider self-report record	115 (63.5)
Direct observation	106 (58.6)
Participant interview	106 (58.6)
Provider interview	81 (44.8)
Participant self-report record	73 (40.3)
Audio recording	67 (37)
Participant follow up visits	57 (31.5)
Exit questionnaires	56 (30.9)
Video recording	27 (14.9)
None	1 (0.6)

FIDELITY STRATEGIES	N (%)
Other	8 (4.4)
Simulated patients	1 (0.6)
Audit or chart review	2 (1.1)
Web analytics (digital interventions)	3 (1.7)
Blood tests	1 (0.6)
Use of validated fidelity measures	1 (0.6)

Survey findings – enhancement strategies identified

FIDELITY STRATEGIES	N (%)
Training manual	148 (81.3)
Reminder checklists	137 (75.3)
Treatment manual/scripted curriculum/standard operating procedures	118 (64.8)
Protocol review group	84 (46.2)
None	4 (2.2)
Other	7 (3.8)
Ongoing support/supervision for providers	2 (1.1)
Observation/audit of providers delivering intervention	3 (1.6)
Colour coding materials for providers	1 (0.5)
Interim analysis	1 (0.5)

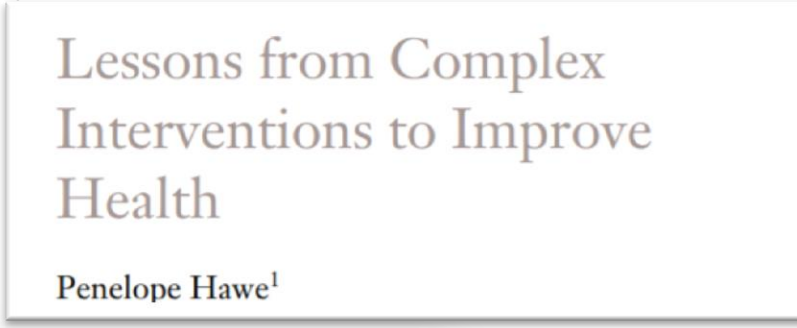
Quality of fidelity assessment strategies

- Psychometric qualities - reliability and validity
- Implementation qualities – acceptability, practicality and cost

- Rixon et al 2016 - assessment of **receipt**
  - 90.0% = subjective assessments of receipt only
  - 26.0% reported on the reliability or validity
- Walton et al – assessment of **delivery**
  - 84.1% reported either reliability or validity
  - 27.3% reported implementation quality

Fidelity and adaptation

- Fidelity **versus** adaptation/flexibility?
  - Form or function?
  - Theory or content?
  - Adherence or competence?


Lessons from Complex Interventions to Improve Health

Penelope Hawe[1]

that standardization should be conducted in a different way (67). They suggest that the form that the components take may vary across sites, but the function that they perform in the local context is always the same. Standardizing by function, rather than by form, requires investigators to consider the role that a component plays in the overall change process (67). Standardizing by function is the chief means by which a complex intervention is allowed to adapt to local context without sacrificing fidelity. Fidelity resides in the theory of the change process, rather than in any particular technology, component, or delivery channel per se. Thus, the role and meaning behind a particular component, rather than its face value, are what matter. Local-level adaptation is important for maximizing effects and encouraging ongoing sustainability (15, 107, 108). Byng and

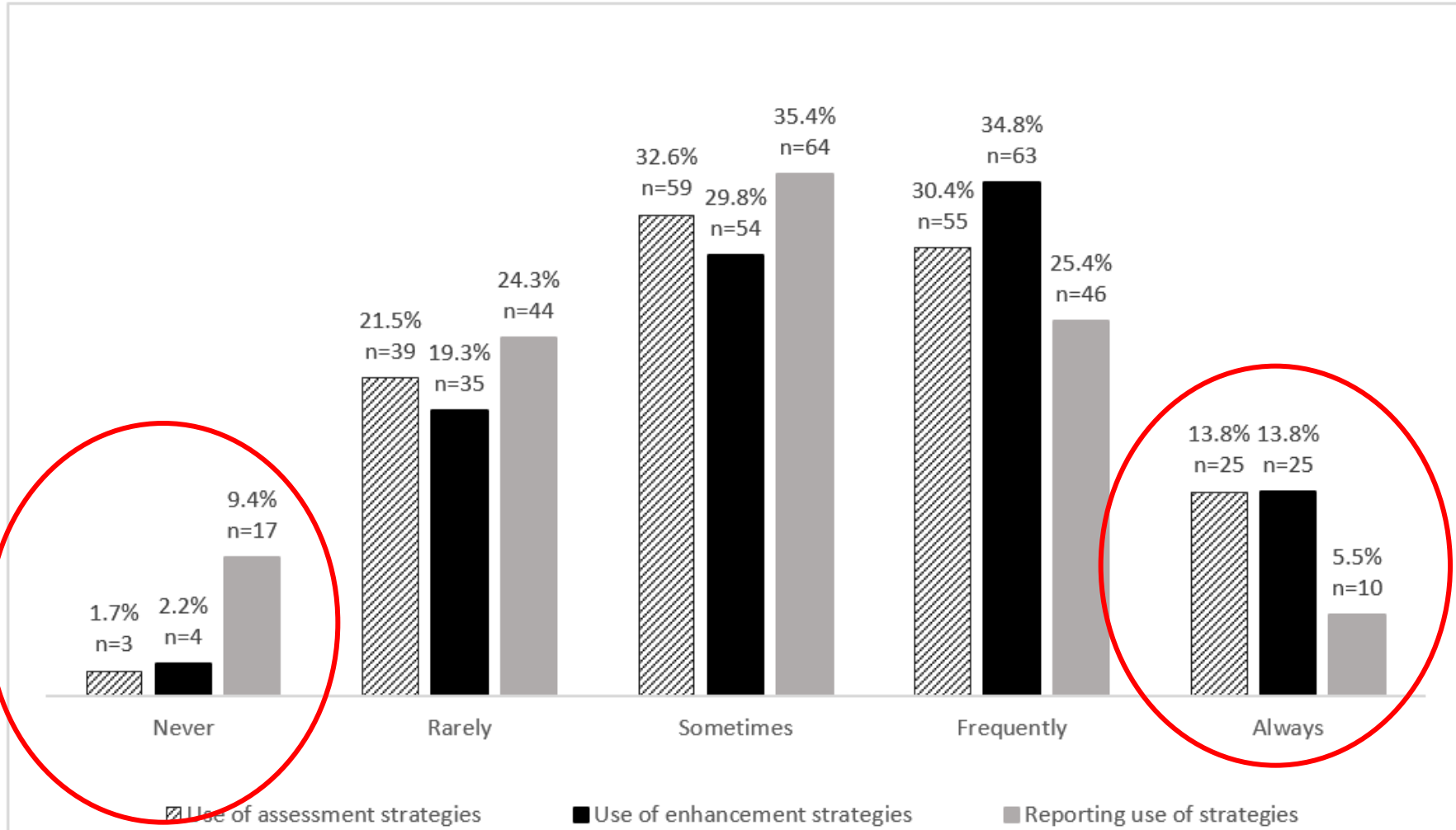
Reporting of intervention fidelity

- Reporting of use of
- Reporting results o
- Limitation of all rev
  support this

conceptualisation and nomenclature. However, it must also be acknowledged that conduct and reporting are two distinct concepts (Leeden et al., 2014), and while the fidelity of the included studies may not necessarily be poor, its reporting clearly is. Although key reporting guidelines exist for the reporting and publication of clinical trials as the CONSORT (Schulz et al., 2010) and TREND (Des Jarlais et al., 2004) statements, only the latter refers briefly to fidelity but does not give specific guidance as to *how* it should be reported within trials. Some of the aspects of the CONSORT and TREND checklists overlap with components on the NIHBCC fidelity checklist (e.g. content and dosage of intervention), but there are a number of elements that they do not address, such as the use of treatment manuals and details of provider training. This overlap is illustrated by the fact that only three studies explicitly reported addressing fidelity (Hughes et al., 2004, 2006; Johnson et al., 2007; Coleman et al., 2012), yet all included studies addressed some aspect of fidelity, more than likely as coincidental standard trial reporting required by the CONSORT and TREND guidelines. As yet,

McGee et al. (under review)

Figure 2: Frequency of use of assessment strategies, enhancement strategies and reporting



Activity 2

Activity 2 feedback

- What are the difficulties?
  - Overlap between enhance and assess? Receipt and enactment?
  - Practicalities - what to do if resources limited?
    - Key uncertainties?
    - Sampling based on sites etc?
    - Theoretical fidelity v content?
- What else might you want to include?
  - Existing fidelity measures (e.g. Motivational Interviewing)
  - Influences of context on intervention fidelity?
  - Mechanisms of action?
- How and what will you report?

livery.[24] It is therefore important to strike a balance between idealism (comprehensive assessment) and pragmatism (feasibility). Therefore, we recommend that researchers identify the key uncertainties regarding intervention fidelity, for example, fidelity of delivery across sites or between providers, and use comprehensive methods to enhance and assess these specific aspects, rather than attempting to address all aspects of fidelity. Instead

Research Report

Training of providers	Description of how providers will be trained (manual of training procedures)	✓ Yes	A standardized training manual detailing content, structure, timing, and setting will be used by the research team to deliver the training. Scripted role plays will be used. Predeveloped written case studies will be used. The development of training of providers enhancement strategies will be detailed fully elsewhere.	The content, structure, timing, setting, and number and characteristics of trainers will be recorded on a posttraining record form, which will be completed by the research team trainers subsequent to the training. The development of training of providers assessment strategies will be detailed fully elsewhere. Audio recordings of role plays used during the training will be conducted.
	Standardization of provider training (especially if multiple waves of training are needed for multiple groups of providers)	✓ Yes	A standardized training manual detailing content, structure, timing, and setting will be used by the research team to deliver the training for each training wave. For each wave, providers from all sites will attend the same training. Scripted role plays will be used. Predeveloped written case studies will be used.	The content, structure, timing, setting, and the number and characteristics of trainers will be recorded on a posttraining record form, which will be completed by the research team trainers subsequent to the training. Audio recordings of role plays used during the training will be conducted.

management for people with chronic low back pain or osteoarthritis.

Design. A 2-phase mixed-methods design was used.

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), School of Public Health, Physiotherapy and Sports Science, Health Sciences Centre, University College Dublin.

			acceptability and appropriateness of the intervention and materials and to refine the intervention for subsequent waves if necessary.	

Lorencatto *et al. Implementation Science* (2016) 11:163
DOI 10.1186/s13012-016-0528-x

STUDY PROTOCOL

A multidimen
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Fabiana Lorencatto[1*], Natalie J.
Robert Cicero[3], Liz Glidewell[3], S
Susan Michie[6], Jill J. Francis[1] an

Table 1 BCC fidelity dimensions (Bellg et al. [11]) and their application in the AFFINITIE trial

Fidelity dimensions	Application intervention 1 (enhanced content—feedback reports)	Application intervention 2 (enhanced follow-on support—web-based toolkit + telephone support)
Design		
Provide information about treatment dose in intervention and control/comparison condition: length of contacts (min), number of contacts, content of treatment, duration of contact over time	• Intervention content and delivery parameters described in separate intervention development papers for each intervention • Description of intervention content in terms of component behaviour change techniques (BCTs) using established BCT taxonomy • Treatment differentiation: comparison of BCTs between both interventions and between each intervention and corresponding current standard practice comparator. BCTs will be compared in terms of frequency, mode of delivery, behavioural specificity and enactment instruction. BCTs that are identified at least once in either intervention and/or comparator will be classified as either fully convergent (present in similar frequency/mode of delivery/behavioural specificity/enactment instruction in both intervention/comparator), partially convergent (present in both, but at different frequencies/ modes of delivery/ behavioural specificity/ enactment instruction) or unique (present in only intervention or comparator). The percentage of BCTs in each category will be assessed, with a higher proportion of fully/partially convergent BCTs indicating lower treatment differentiation.	
Method to ensure dose is equivalent between conditions.	• Hospitals in the intervention and control trial arms for intervention 1 will both receive at least one feedback report and feedback PowerPoint presentations as per standard practice. • However, dose may differ in terms of the number of feedback reports received per condition, as the enhanced feedback report condition includes multiple feedback reports following a graded entry approach (i.e. level 1—key findings → level 3—detailed supplementary findings report).	• N/A; All hospitals randomised to the enhanced condition for intervention 2 will receive the toolkit and initial telephone support at equivalent doses. However, hospitals in the control condition for intervention 2 will not receive an equivalent dose of intervention 2 as the comparator is a standard practice/no intervention condition.
Method to ensure dose is equivalent for participants within conditions.	• The enhancement guidance manual will be used to produce a report template containing the proposed enhancements, which will be populated with hospital specific data for each hospital. Using a template report will help ensure the format and content of reports is consistent across hospital specific reports.	• The same web-based toolkit will be delivered to all intervention 2 hospitals. Dose is standard within condition. • All hospitals will receive one initial facilitator-initiated telephone support call.
Specification of intervention provider credentials that are needed	• Described under *training* dimension	
Theoretical model upon which the intervention is based is clearly articulated: - The active ingredients are specified and incorporated into the intervention. - Use of experts or protocol review group to determine whether the intervention protocol reflects the underlying theoretical model or clinical guidelines.	• Intervention causal assumptions, theory (control theory) and evidence base (Cochrane audit and feedback review) summarised in logic models reported in intervention development papers. • Component BCTs in each intervention mapped onto control theory • Interventions developed in collaboration with multidisciplinary consensus panel (transfusion clinical staff, behavioural scientists, patient representatives) to ensure the interventions reflect the underlying theoretical models and hold clinical face validity	
Potential confounders that limit the ability to make conclusions at the end of the trial are identified.	• Possible contamination threats (e.g. regional transfusion committee meetings) will be continuously monitored and documented throughout the AFFINITIE trials. • Wider contextual factors external to the AFFINITIE trials that may influence intervention outcomes will be examined via the process evaluation (e.g. publication of new NICE transfusion clinical guidelines).	
Plan to address possible contacts in	NUI Galway and the National	NUI Galway and the National

NUI Galway
OÉ Gaillimh

Final fidelity thoughts…

- Use a framework/existing tools
- Think about fidelity as more than delivery
- Clarify how you are defining/conceptualising it
- Consider both enhancement and assessment strategies
- Assessment strategies - comprehensiveness v feasibility
  - How much/how many to assess? Purposive sampling?
  - Consider psychometric (reliability, validity) and implementation (feasibility) properties of assessment measures
  - Existing measures?
  - Mixed methods
  - Objective and subjective
- Reporting and further action

3. Application

to own context

Conclusions

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HEALTH BEHAVIOUR CHANGE RESEARCH GROUP

Email: molly.byrne@nuigalway.ie; elaine.toomey@nuigalway.ie

Twitter: @MollyByrneIre @hbcrg @oonaghmeade @ElaineToomey1

Website: http://www.nuigalway.ie/hbcrg/

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