Models, frameworks and theory for program design, implementation and evaluation

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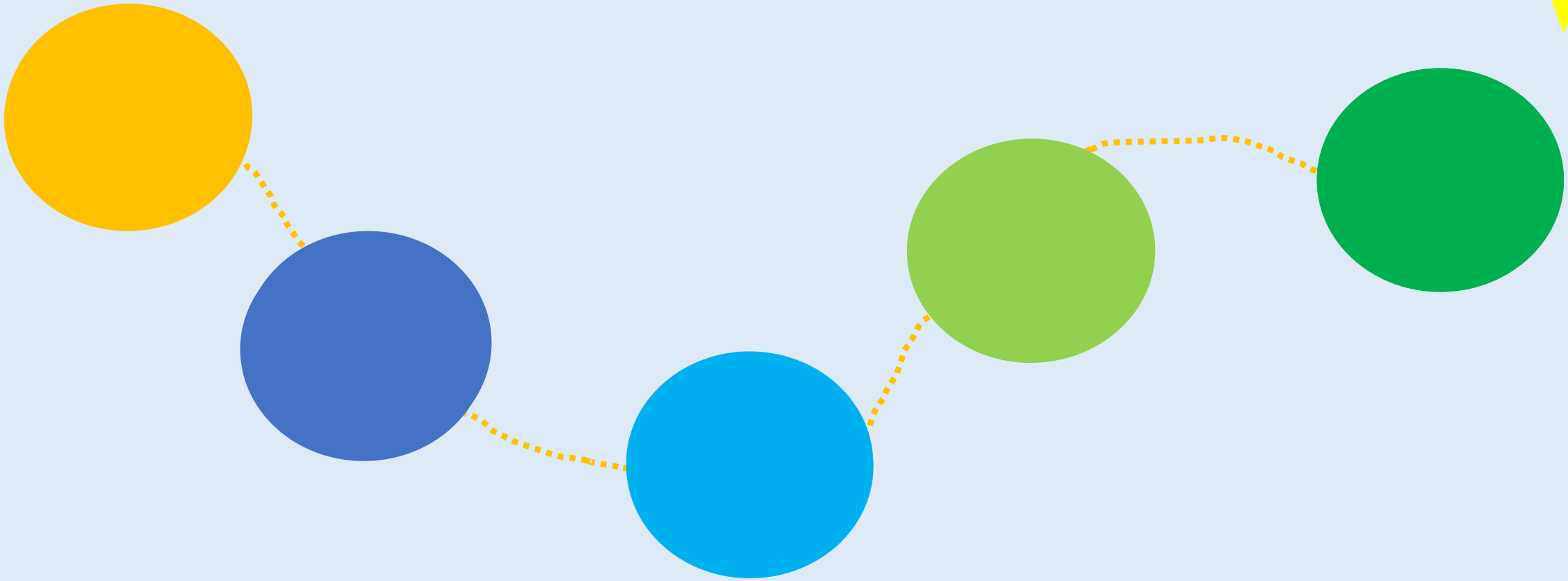
This talk:



Year 2001: Type 2 Diabetes Recognized as a Global Health Problem

- Diabetes is the fourth leading cause of disease
- Over
  incre
- Over
  worl

- health
- The Finnish Diabetes Prevention Study (Fin- DPS)[1]:
  festyle modification prevents T2D
  and some other prevention trials[2]:
  style modification even more effective than drug
  tment
  China, IDPP in India, Japanese Prevention Trial[3]:
  isk significantly reduced despite small overall changes in
  tterns

[1]Tuomilehto ym. (2001). Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. New England Journal of Medicine, 344, 1343-1350.

[2]Knowler ym. (2002). Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. New England Journal of Medicine, 346, 393-403

[3]Pan et al., 1997, Ramachandran et al., 2006, Kosaka et al., 2005

How to replicate T2D prevention efficacy trial results in real world?

- What is the behavior change mechanism?
- How can the intervention be implemented in routine care?

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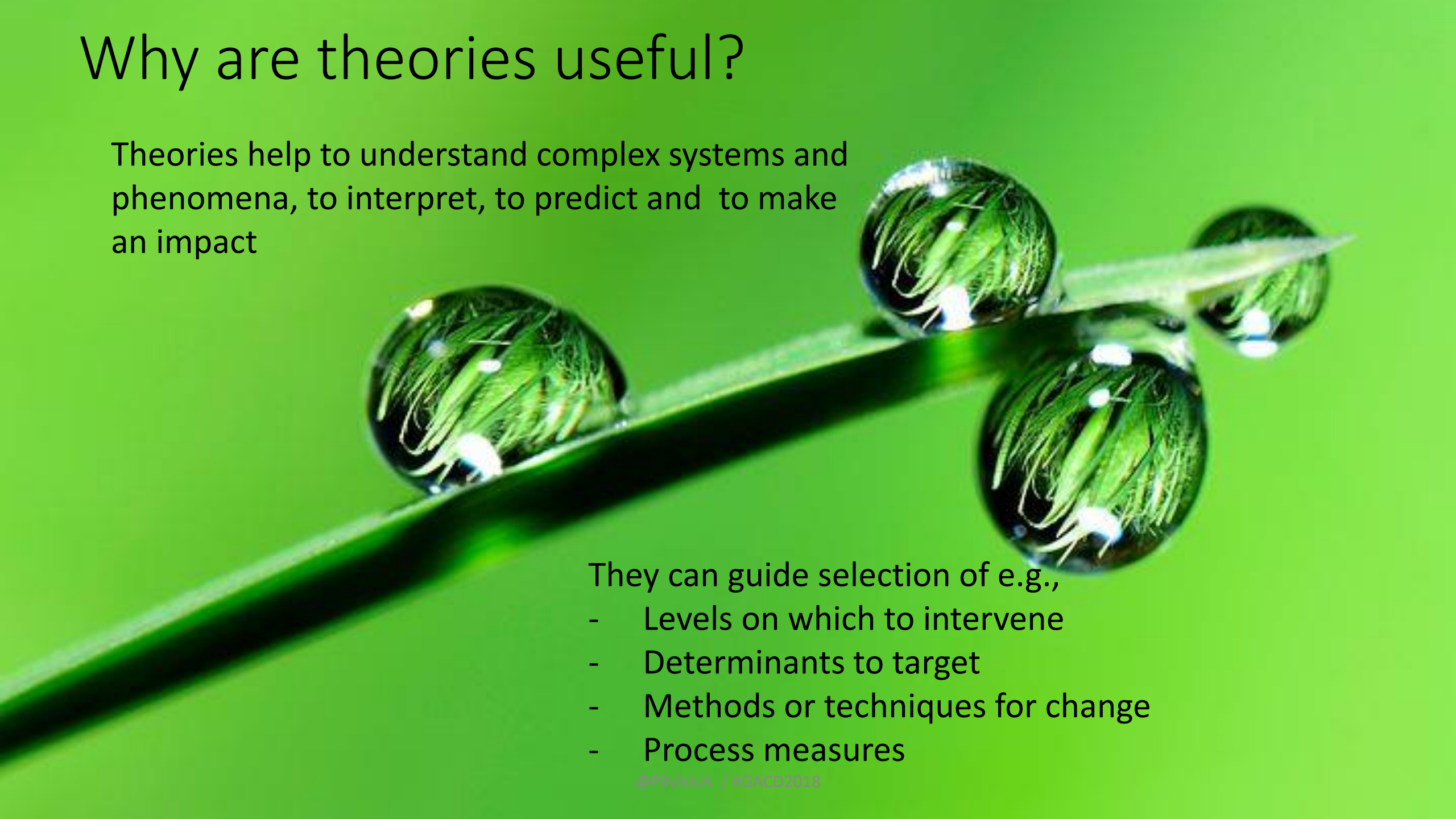
Where is the MAIN focus of intervention?

- Participant-level intervention – changing lifestyle?
- Provider-level intervention – changing nurse's way of counseling patients?
- System-level intervention – changing the entire preventive care process, i.e., screening, intervention, follow-up of people at risk?

Why are theories useful?

Theories help to understand complex systems and phenomena, to interpret, to predict and to make an impact



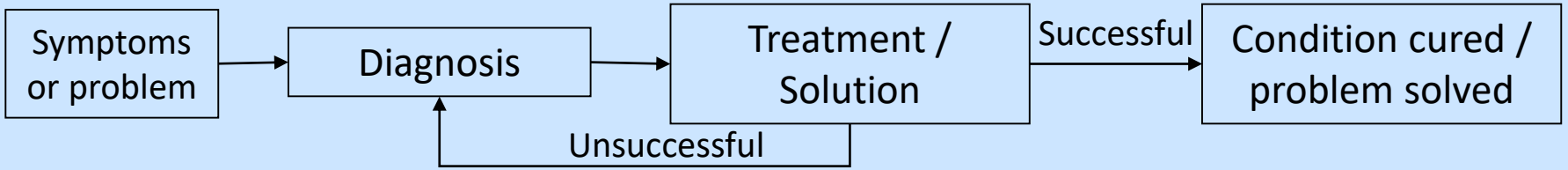
They can guide selection of e.g.,

- Levels on which to intervene
- Determinants to target
- Methods or techniques for change
- Process measures

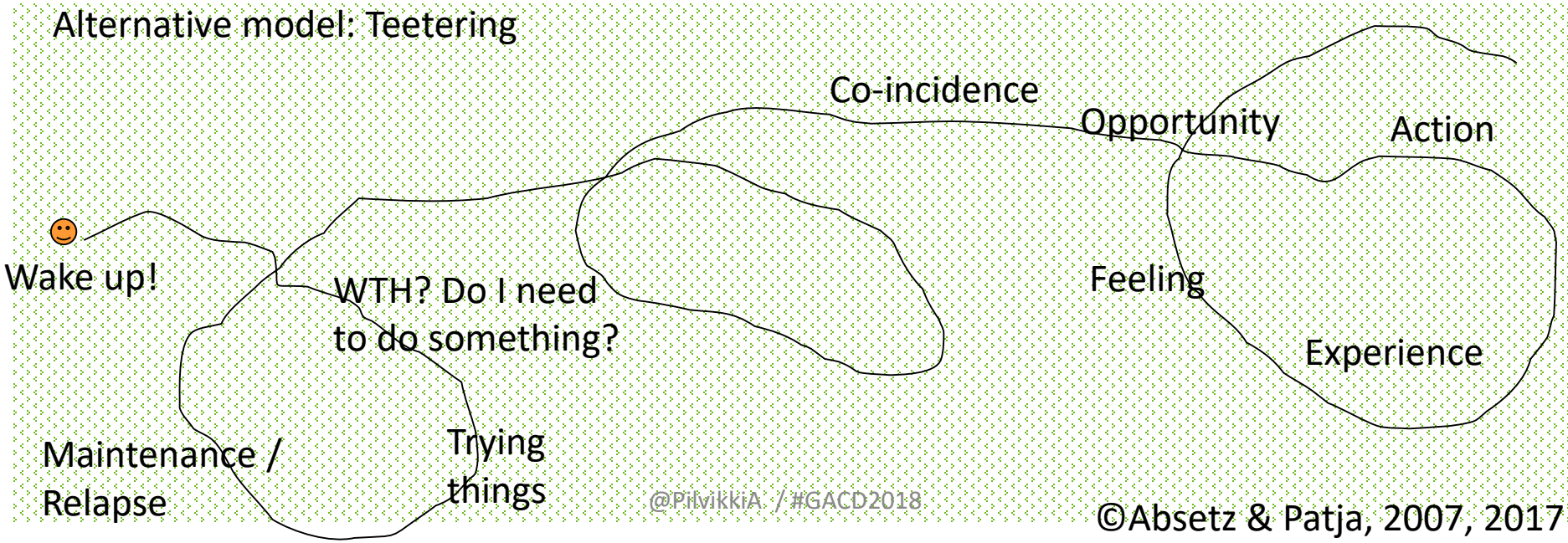
We all have theories, but often without recognizing them…

When implicit theories fail: Lifestyle change

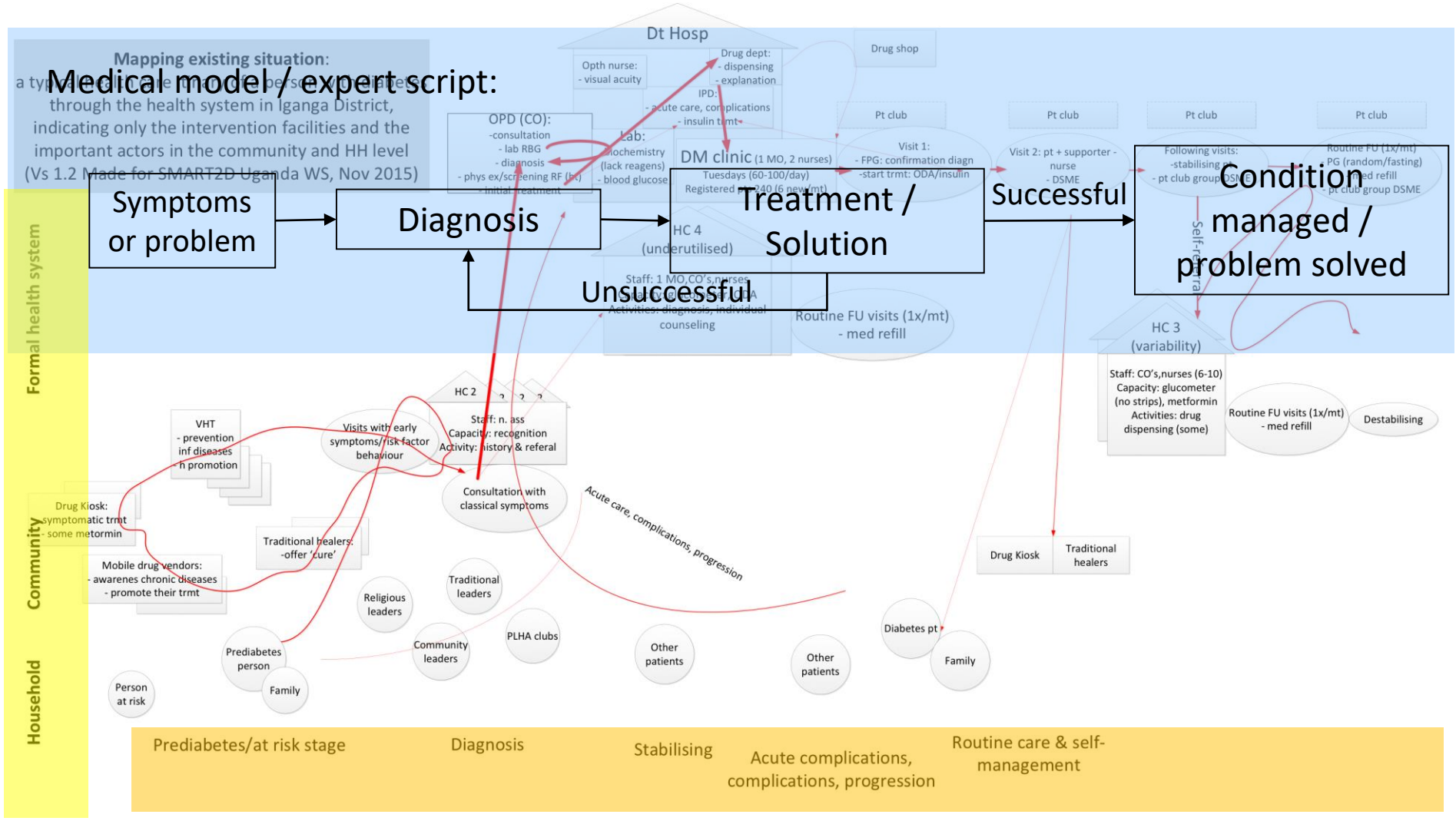
Medical model / expert script:



Alternative model: Teetering



When implicit theories fail, T2D Care Process



Suggested criteria for a good theory:

1. Clarity of theoretical concepts
2. Clarity of relationships between constructs
3. Measurability
4. Testability
5. Being explanatory (statistically or logically)
6. Describing causality
7. Achieving parsimony
8. Generalisability
9. Having an evidence base

Michie S, West R, Campbell R, et al. An ABC of behaviour change theories. London: Silverback Publishing, 2014.


@PiivikkiA - #GACD2018

”Theories, models and frameworks” (TMF)

- Practically impossible to give a satisfactory and mutually exclusive definition of these three terms
- Good to recognize:
  - Theory-based: research testing a specific theory or theoretical propositions
    - Makes explicit the assumptions on which programs are based,
    - Links assumptions with what the program does (activities) and with the expected effects
  - Informed or guided by theory: following from theory but not testing it
  - Generalizability of theory across settings and contexts?

My thinking of TMF in implementation science

- Useful to separate 3 functions
  - To describe / map the process that guides translating research into practice or to another context (e.g., Intervention Mapping, Method for Program Adaptation through Community Engagement (M-PACE)
  - To identify determinants and mechanisms of change at different levels (e.g., Precede/Proceed, Theoretical Domains Framework, COM-B, Normalization Process Theory, Organizational Readiness, Diffusion of Innovations)
  - To guide comprehensive evaluation of implementation and covering acceptability, reach, adoption, fidelity, implementation cost and sustainability. (e.g., RE-AIM, PIPE, TFA)
- NB. Even this might be an artificial categorization!
- NB 2. Some TMF tap more than 1 function
- NB 3. Upstream theories are underrepresented in this presentation, and also in the field of implementation science

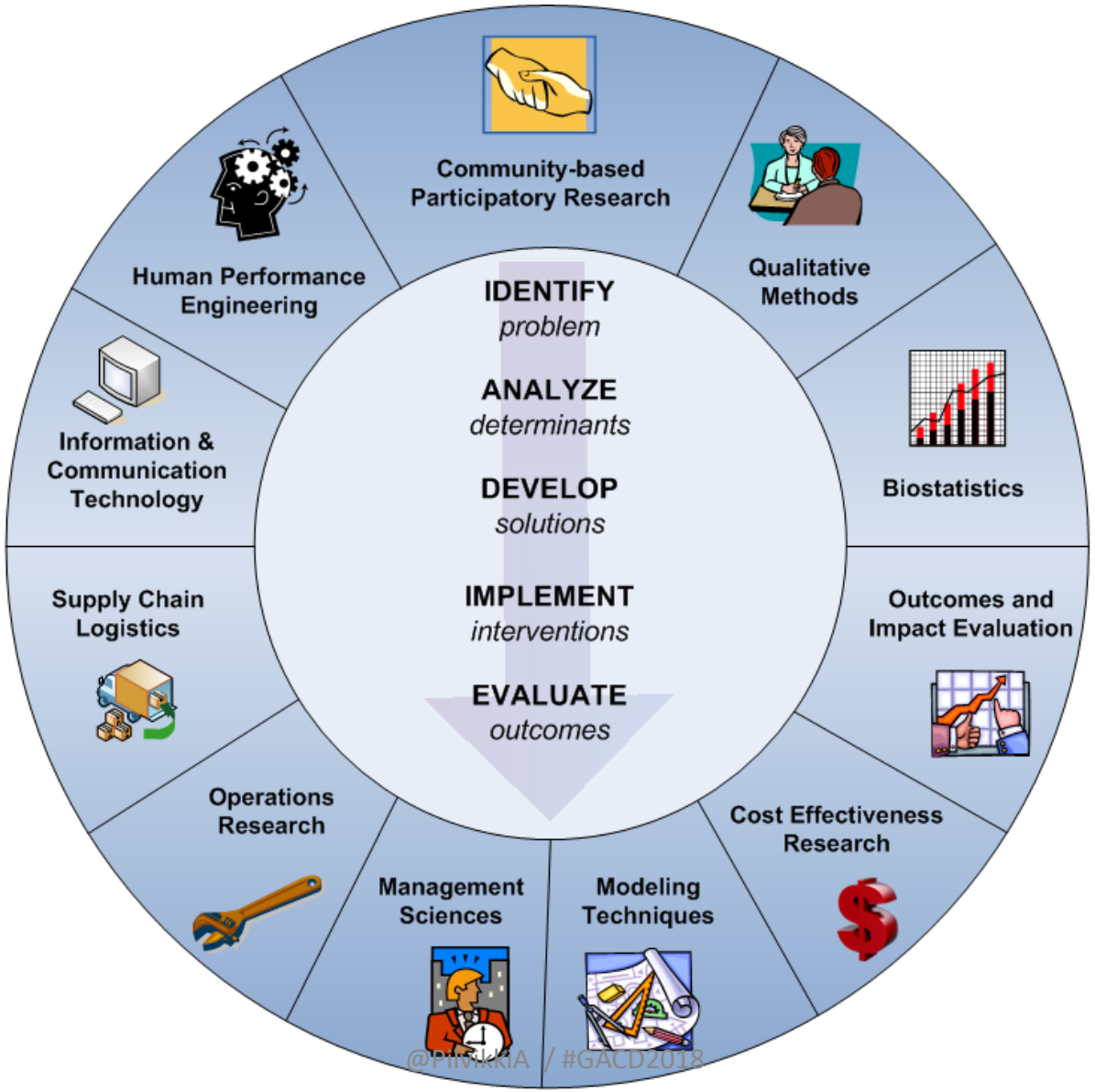
PART 1: TMF to map the process to translate research into practice or to another context

Intervention Mapping

1. **Needs Assessment**
2. **Matrices:** Define what (behavioral or environmental) changes you want to achieve and what are the underlying **determinants**
3. Select the best **theoretical methods** and the most feasible **practical strategies**
4. Plan: How will the **program** look like?
5. Plan: How will the program be **adopted and implemented**?
6. Plan: How can the program be **evaluated**?

Bartholomew et al. PLANNING HEALTH PROMOTION PROGRAMS – An Intervention Mapping Approach. 4th Ed. Jossey-Bass, 2016.
https://interventionmapping.com/

Implementation Research “Cartoon”



Vedanthan (2011) MSJM

Standardization by function rather than by program content
(Prof Ed Fisher, UNC)

Mathews et al. BMC Public Health (2017) 17:974
DOI 10.1186/s12889-017-4986-0

BMC Public Health

RESEARCH ARTICLE Open Access

Cultural adaptation of a peer-led lifestyle intervention program for diabetes prevention in India: the Kerala diabetes prevention program (K-DPP)

Elezebeth Mathews[1,2†], Emma Thomas[3*†], Pilvikki Absetz[4,5,6], Fabrizio D'Esposito[3], Zahra Aziz[3], Sajitha Balachandran[1], Meena Daivadanam[7,8], Kavumpurathu Raman Thankappan[1] and Brian Oldenburg[3]

Abstract

Background: Type 2 diabetes mellitus (T2DM) is now one of the leading causes of disease-related deaths globally. India has the world's second largest number of individuals living with diabetes. Lifestyle change has been proven to be an effective means by which to reduce risk of T2DM and a number of "real world" diabetes prevention trials have been undertaken in high income countries. However, systematic efforts to adapt such interventions for T2DM prevention in low- and middle-income countries have been very limited to date. This research-to-action gap is now widely recognised as a major challenge to the prevention and control of diabetes. Reducing the gap is associated with reductions in morbidity and mortality and reduced health care costs. The aim of this article is to describe the adaptation, development and refinement of diabetes prevention programs from the USA, Finland and Australia to the State of Kerala, India.

Methods: The Kerala Diabetes Prevention Program (K-DPP) was adapted to Kerala, India from evidence-based lifestyle interventions implemented in high income countries, namely, Finland, United States and Australia. The adaptation process was undertaken in five phases: 1) needs assessment; 2) formulation of program objectives; 3) program adaptation and development; 4) piloting of the program and its delivery; and 5) program refinement and active implementation.

Results: The resulting program, K-DPP, includes four key components: 1) a group-based peer support program for participants; 2) a peer-leader training and support program for lay people to lead the groups; 3) resource materials; and 4) strategies to stimulate broader community engagement. The systematic approach to adaptation was underpinned by evidence-based behavior change techniques.

Conclusion: K-DPP is the first well evaluated community-based, peer-led diabetes prevention program in India. Future refinement and utilization of this approach will promote translation of K-DPP to other contexts and population groups within India as well as other low- and middle-income countries. This same approach could also be applied more broadly to enable the translation of effective non-communicable disease prevention programs developed in high-income settings to create context-specific evidence in rapidly developing low- and middle-income countries.

Trial registration: Australia and New Zealand Clinical Trials Registry: ACTRN12611000262909. Registered 10 March 2011.

Keywords: Cultural adaptation, Diabetes prevention, Type 2 diabetes mellitus (T2DM), Low and middle income countries (LMICs), Community-based, Peer support, Lifestyle intervention, Implementation

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Adaptation based on stakeholder feedback: the M-PACE model

Systematic processes for 1) obtaining extensive, unbiased participant feedback and 2) making adaptations

Step 1: Convene an Adaptation Steering Committee and familiarize them with the original program

- Researchers, program developers, and community members as equal-status partners in the SC
- SC makes all decisions regarding adaptation

Step 2: Implement the **Unadapted** Program to Generate Recommendations for Program Change

Step 3: Systematically Obtain Evaluations of Program Components

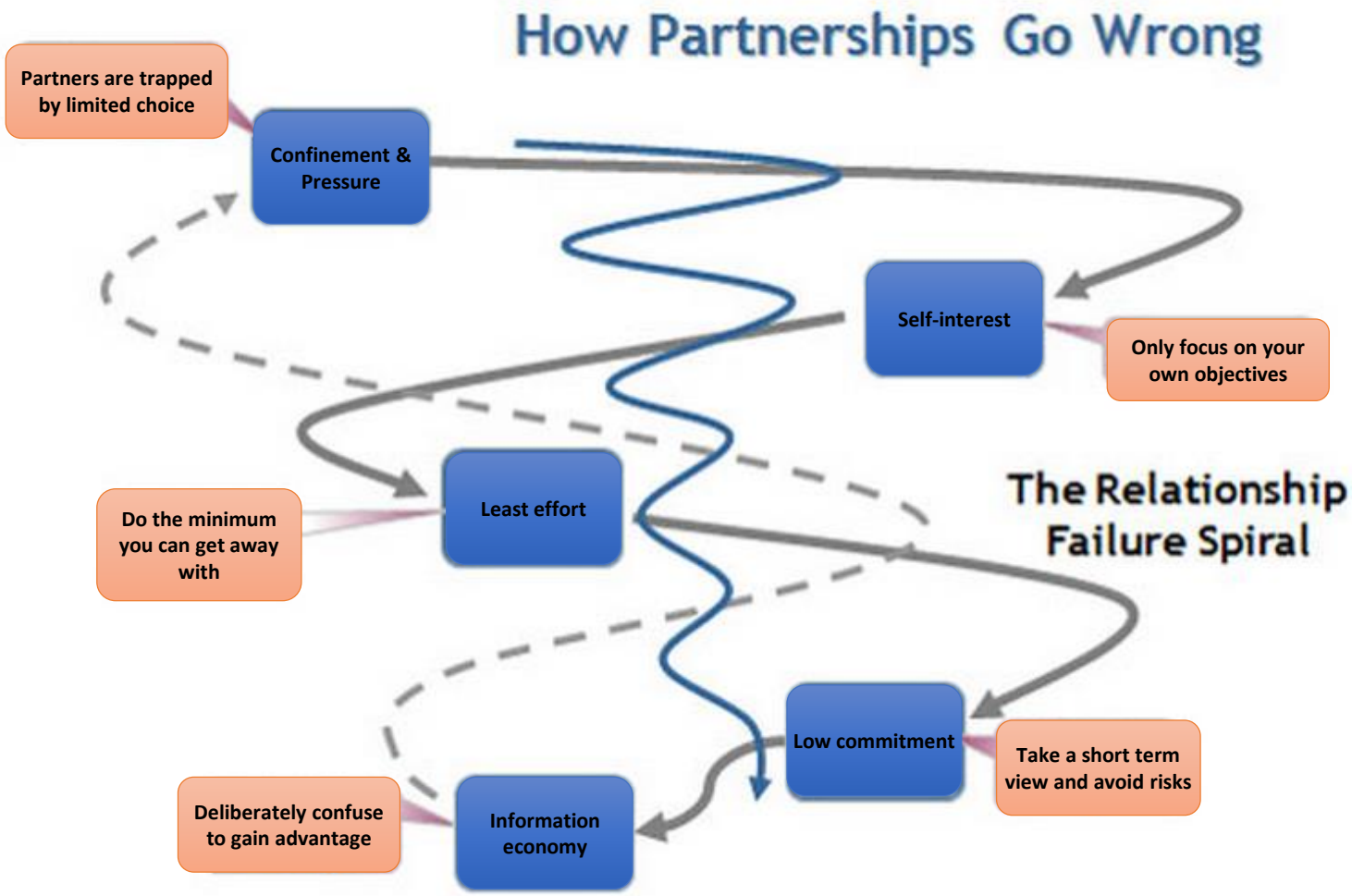
- Survey, focus group, program facilitator feedback…

Step 4: Summarize Stakeholder Feedback for the SC

Step 5: Adjudicate Program Feedback to Select Program Modifications

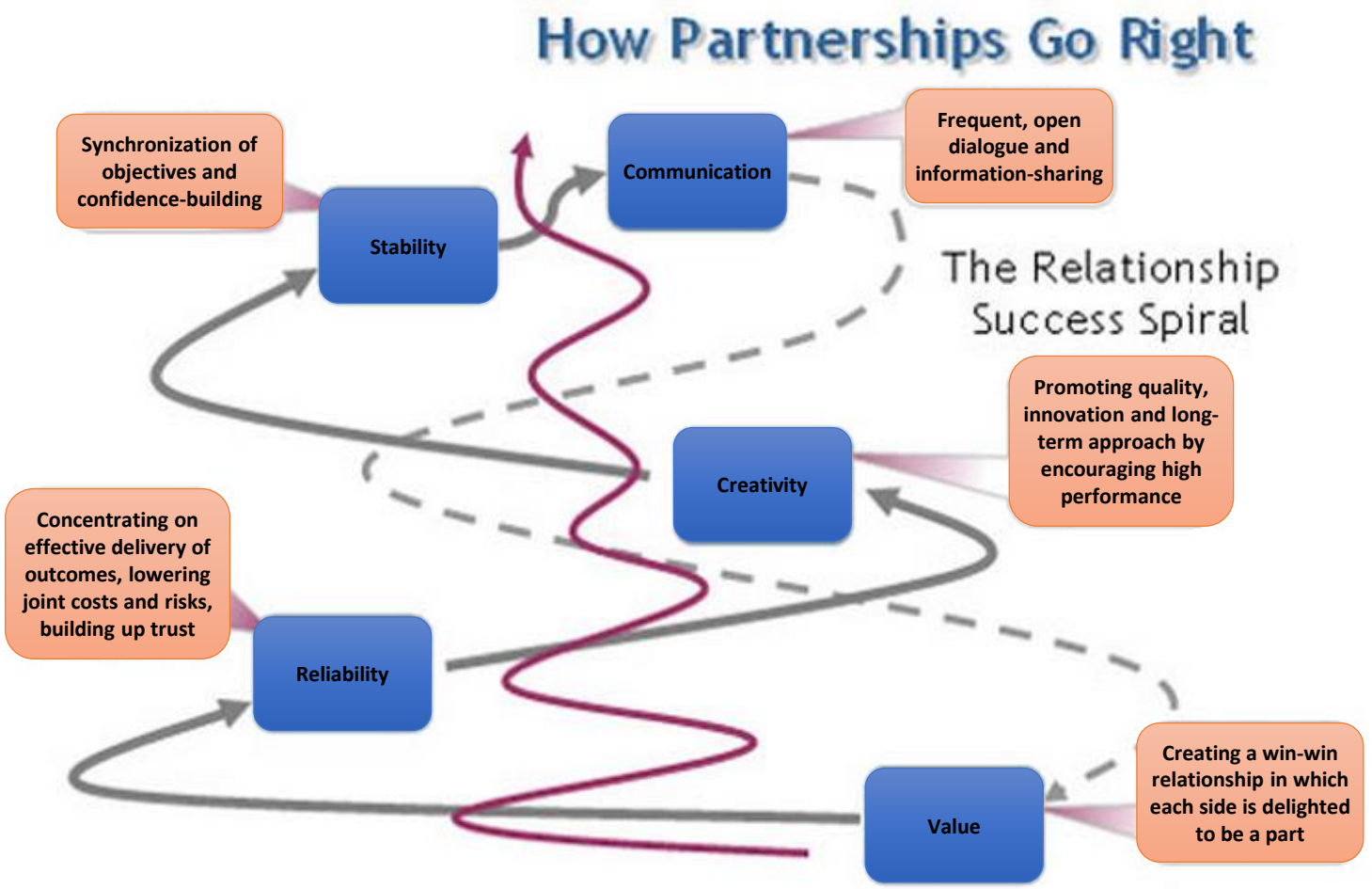
- For any change, SC is required to make a consensus decision based on evaluation of:

✓ Importance – the change will improve program effectiveness and/or reach
✓ Feasibility for participants, representatives of the host site, and program instructors
✓ Congruence as working with, working against, or not interfering with the core components of the evidence-based intervention



Problems may begin with the partners feeling trapped and under pressure. Trapped in the sense that they feel their independence of action is threatened by their commitment to work with the other party. The feeling of entrapment grows and leads each party to take a very self-interested view of the arrangement. This in turn forms the background to adversarial negotiations where "I win, you lose" replaces the notion of "you win, I win".

Source:
www.planstoreality.com.au/images/resource-centre/gaining-competitive-advantage-through-collaboration-and-partnering-fig-1.jpg



Source:
www.planstoreality.com.au/images/resource-centre/gaining-competitive-advantage-through-collaboration-and-partnering-fig-2.jpg

van Olmen J, Delobelle P, Guwatudde D, et al. Using a cross-contextual reciprocal learning approach in a multisite implementation research project to improve self-management for type 2 diabetes. BMJ Glob Health 2018;**0**:e001068. doi:10.1136/ bmjgh-2018-001068 **BMJ Global Health**

SMART2D

Integrated care model

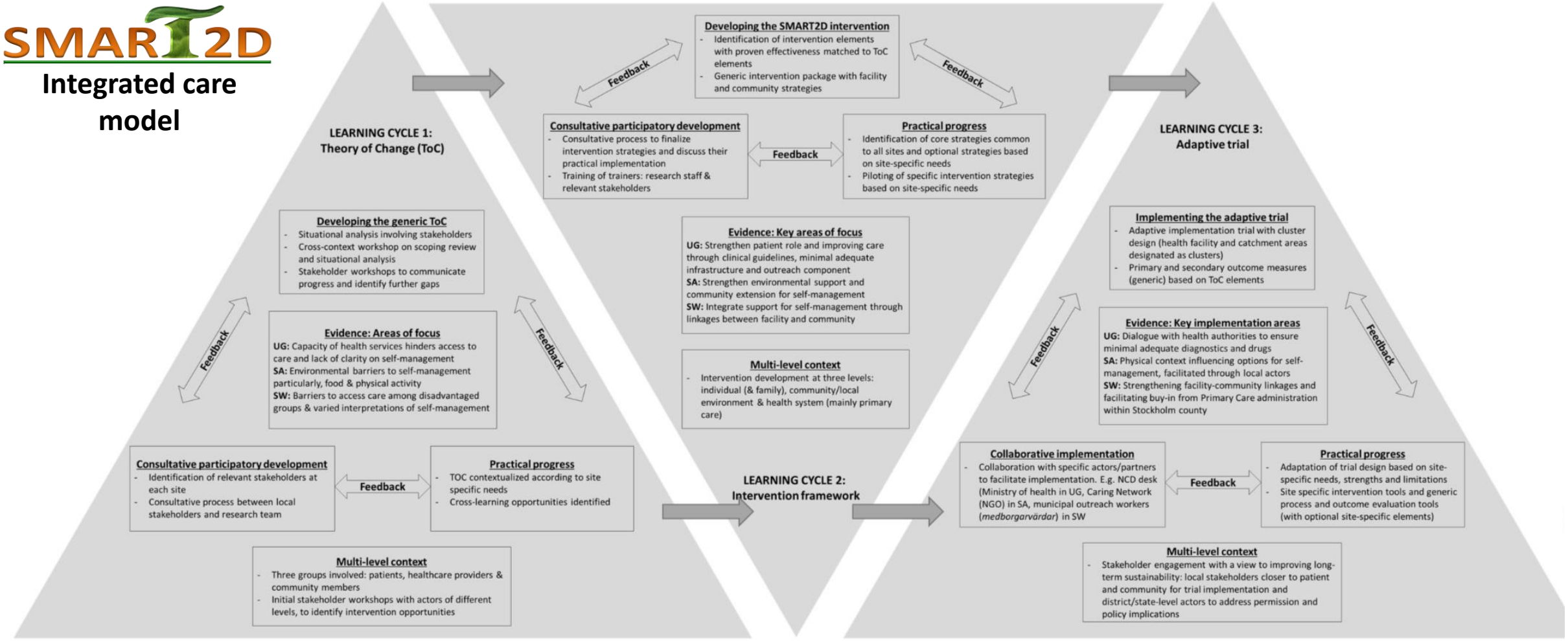
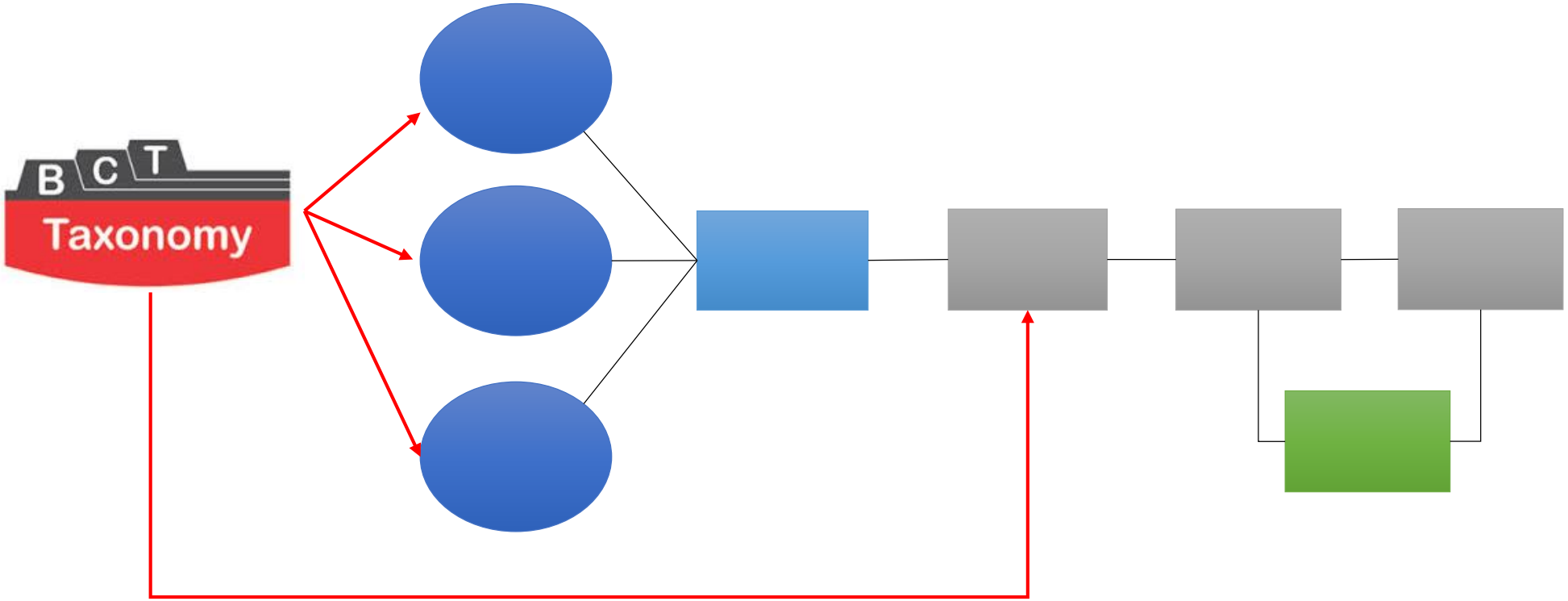
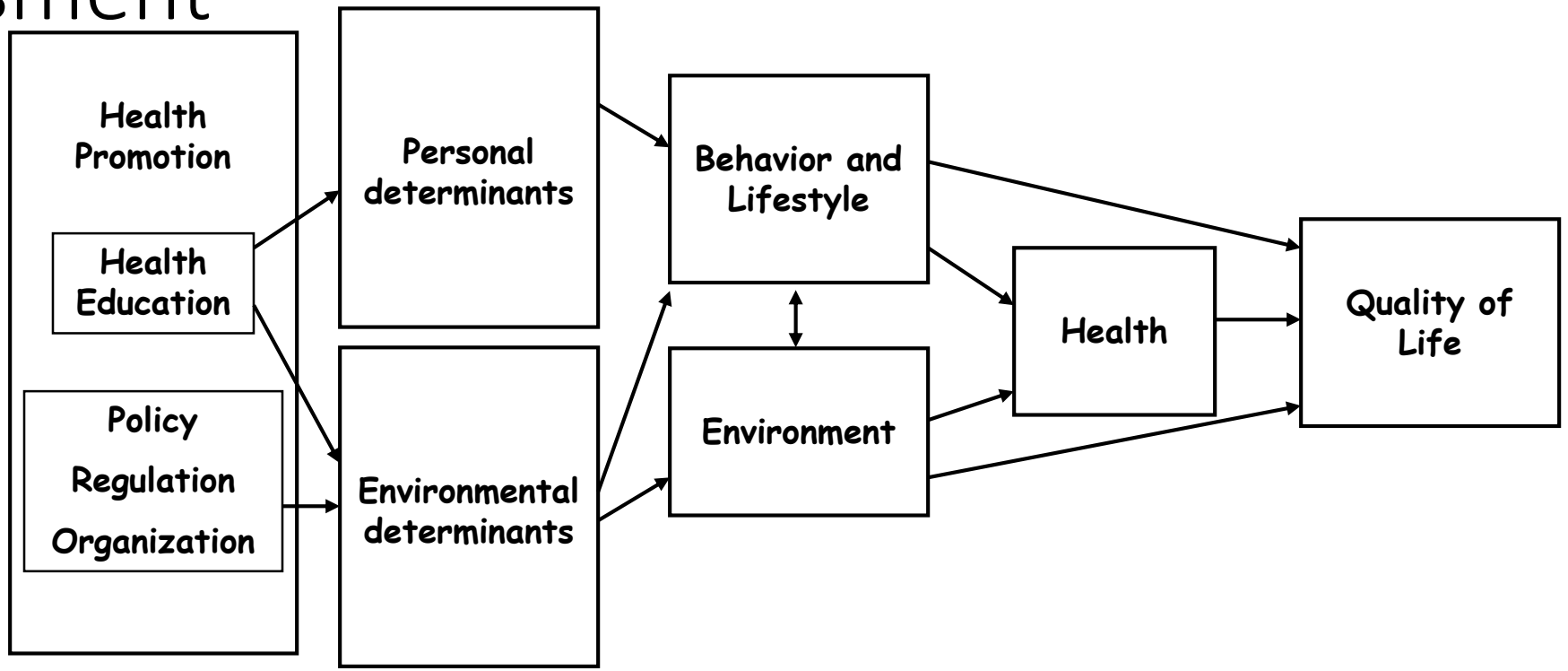


Figure 2 The three learning cycles and reciprocal learning opportunities depicted using the Evidence Integration Triangle. NCD, non-communicable disease; NGO, non-governmental organisation; SA, South Africa; SMART2D, Self-Management Approach and Reciprocal learning for Type 2 Diabetes; SW, Sweden; UG, Uganda.

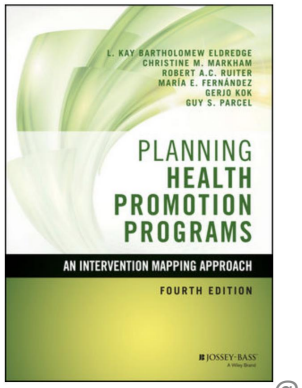
PART 2: TMF to identify determinants and mechanisms of change at different levels



Using theory to conduct IM Step 1: Needs assessment



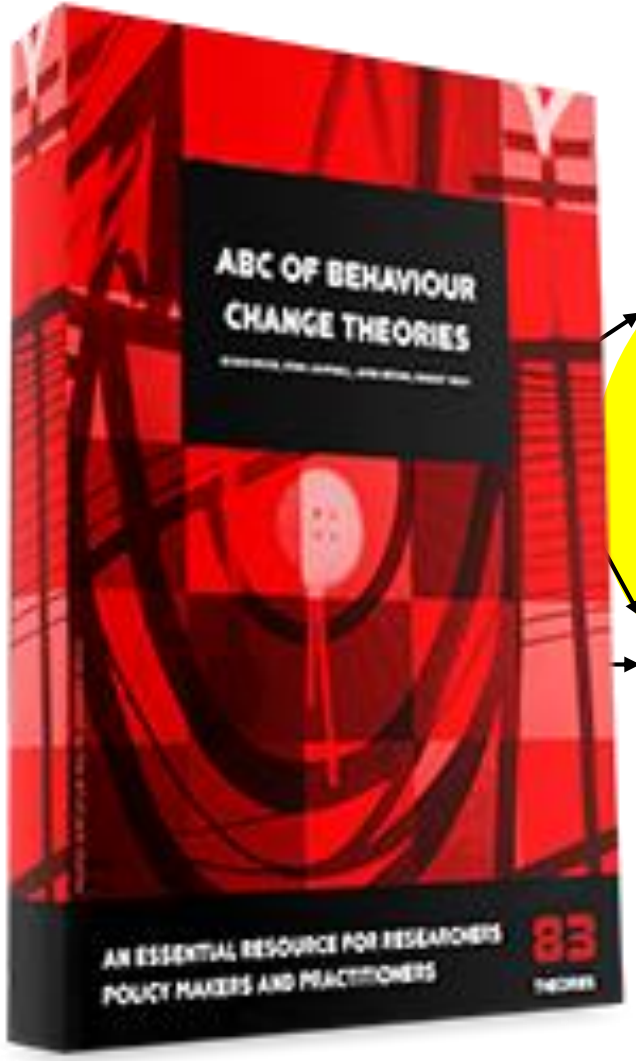
PRECEDE / PROCEED-model by Green & Kreuter; Intervention Mapping (Bartholomew, Parcel, Kok et al.) planning matrix

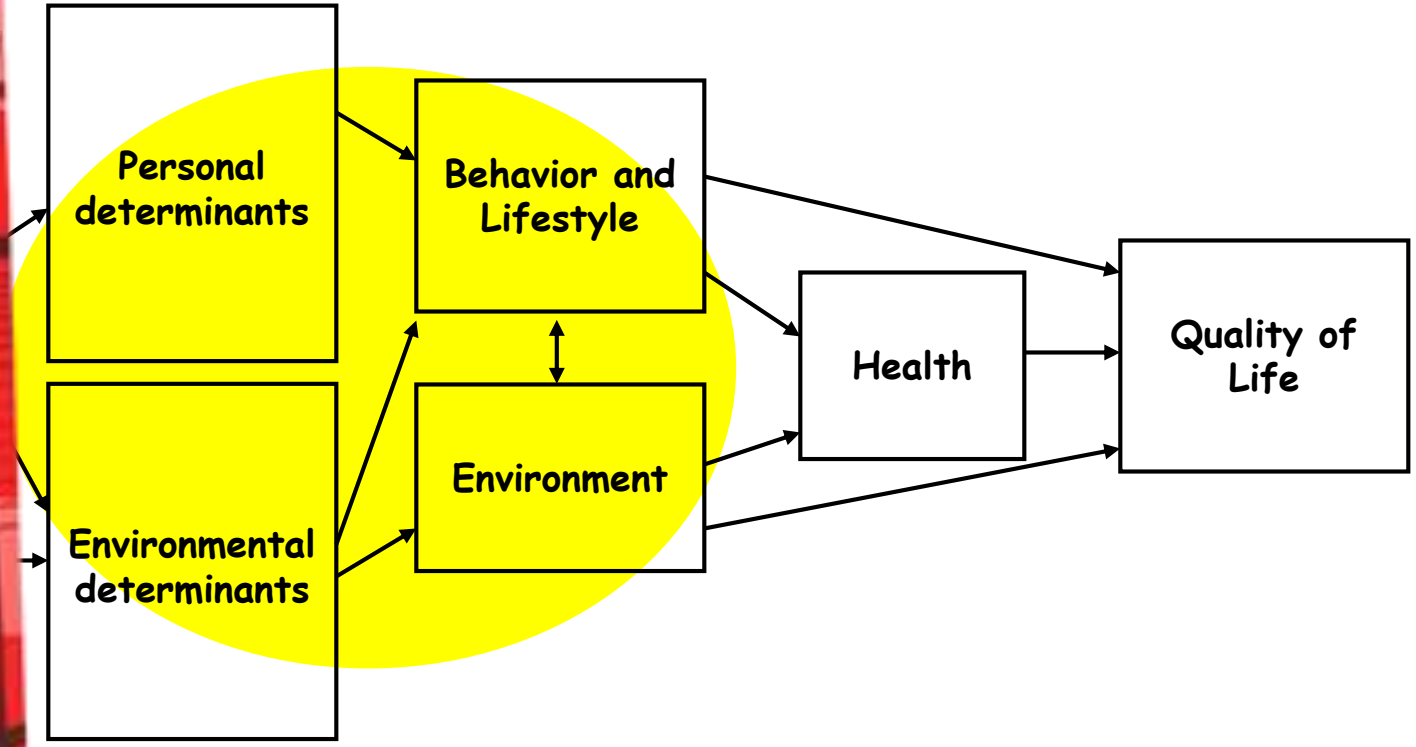


The fourth edition of the Intervention Mapping book

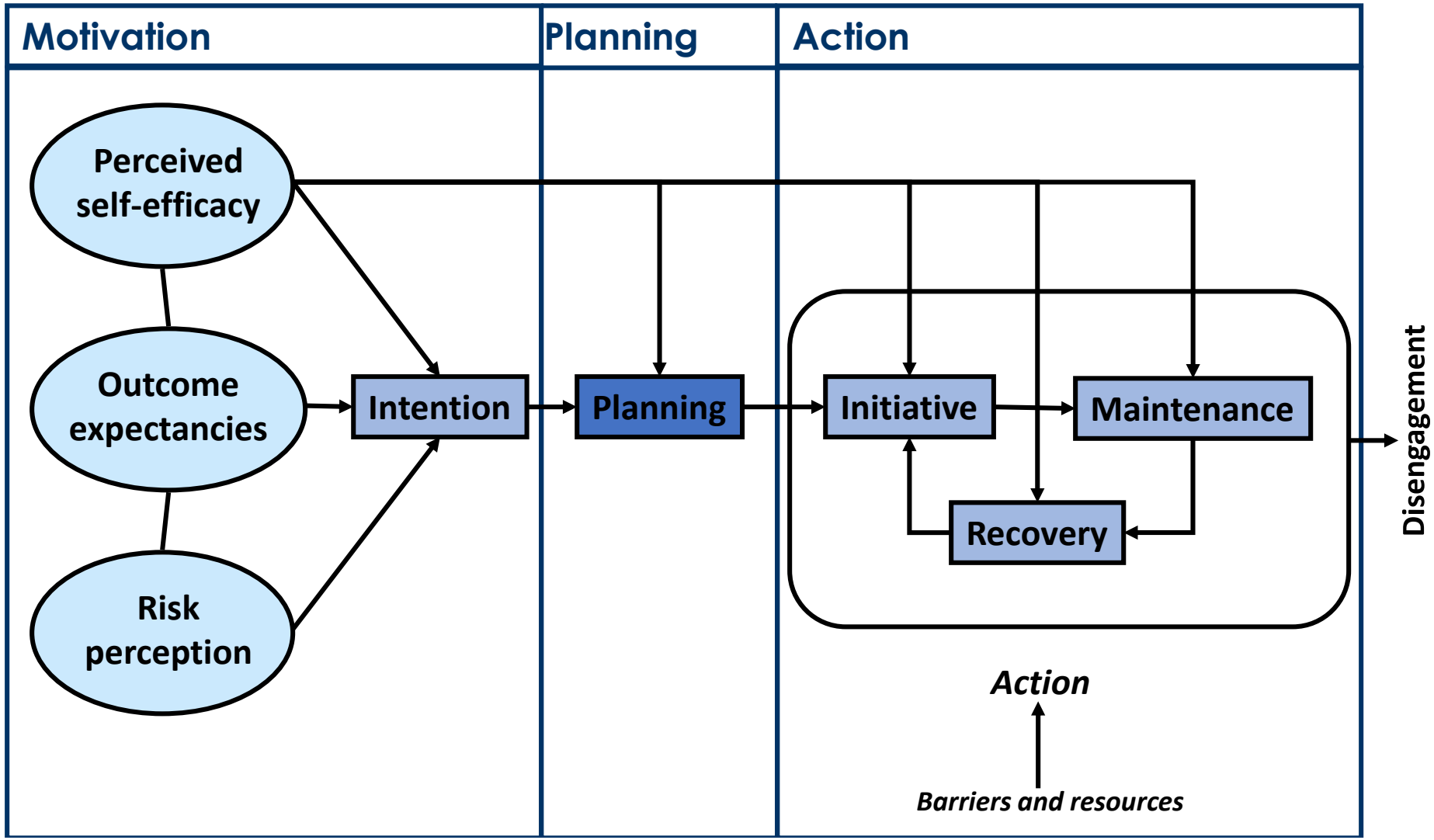
Program objectives	Change objectives	Determinants	Practical strategies (BCT)

Using theory to select determinants





Health Action Process Approach



Schwarzer, R., Fuchs, R. (1996). Self-efficacy and health behaviors. In M. Conner & P. Norman (eds.): Predicting health behaviour: Research and practice with social cognition models (pp. 163-196). Buckingham, UK: Open University Press.

http://www.implementationscience.com/series/TDF

Theoretical Domains Framework

1. Knowledge
2. Skills
3. Social / professional role and identity
4. Beliefs about capabilities
5. Optimi
6. Beliefs
7. Reinfo

- Self-confidence
- Perceived competence
- Self-efficacy
- Perceived behavioural control
- Beliefs
- Self-esteem
- Empowerment
- Professional confidence

8. Intentions
9. Goals
10. Memory, attention and decision processes
11. Environmental context and resources
12. Social influ
13. Emotion
14. Behaviour

- Environmental stressors
- Resources/material resources
- Organisational culture/climate
- Salient events/critical incidents
- Person x environment interaction
- Barriers and facilitators

Benefits of framework

- Covers different potential means of influence
- Makes a distinction between different types of influence
- Links behavior change theories to behavior change techniques

Atkins *et al. Implementation Science* (2017) 12:77
DOI 10.1186/s13012-017-0605-9

Implementation Science

METHODOLOGY **Open Access**

A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems

Lou Atkins[1*], Jill Francis[2,3], Rafat Islam[3], Denise O'Connor[4], Andrea Patey[3], Noah Ivers[5], Robbie Foy[6], Eilidh M. Duncan[7], Heather Colquhoun[8], Jeremy M. Grimshaw[3,9], Rebecca Lawton[10] and Susan Michie[1]

Abstract

Background: Implementing new practices requires changes in the behaviour of relevant actors, and this is facilitated by understanding of the determinants of current and desired behaviours. The Theoretical Domains Framework (TDF) was developed by a collaboration of behavioural scientists and implementation researchers who identified theories relevant to implementation and grouped constructs from these theories into domains. The collaboration aimed to provide a comprehensive, theory-informed approach to identify determinants of behaviour. The first version was published in 2005, and a subsequent version following a validation exercise was published in 2012. This guide offers practical guidance for those who wish to apply the TDF to assess implementation problems and support intervention design. It presents a brief rationale for using a theoretical approach to investigate and address implementation problems, summarises the TDF and its development, and describes how to apply the TDF to achieve implementation objectives. Examples from the implementation research literature are presented to illustrate relevant methods and practical considerations.

Methods: Researchers from Canada, the UK and Australia attended a 3-day meeting in December 2012 to build an international collaboration among researchers and decision-makers interested in the advancing use of the TDF. The participants were experienced in using the TDF to assess implementation problems, design interventions, and/or understand change processes. This guide is an output of the meeting and also draws on the authors' collective experience. Examples from the implementation research literature judged by authors to be representative of specific applications of the TDF are included in this guide.

Results: We explain and illustrate methods, with a focus on qualitative approaches, for selecting and specifying target behaviours key to implementation, selecting the study design, deciding the sampling strategy, developing study materials, collecting and analysing data, and reporting findings of TDF-based studies. Areas for development include methods for triangulating data, e.g. from interviews, questionnaires and observation and methods for designing

COM-B on medication adherence

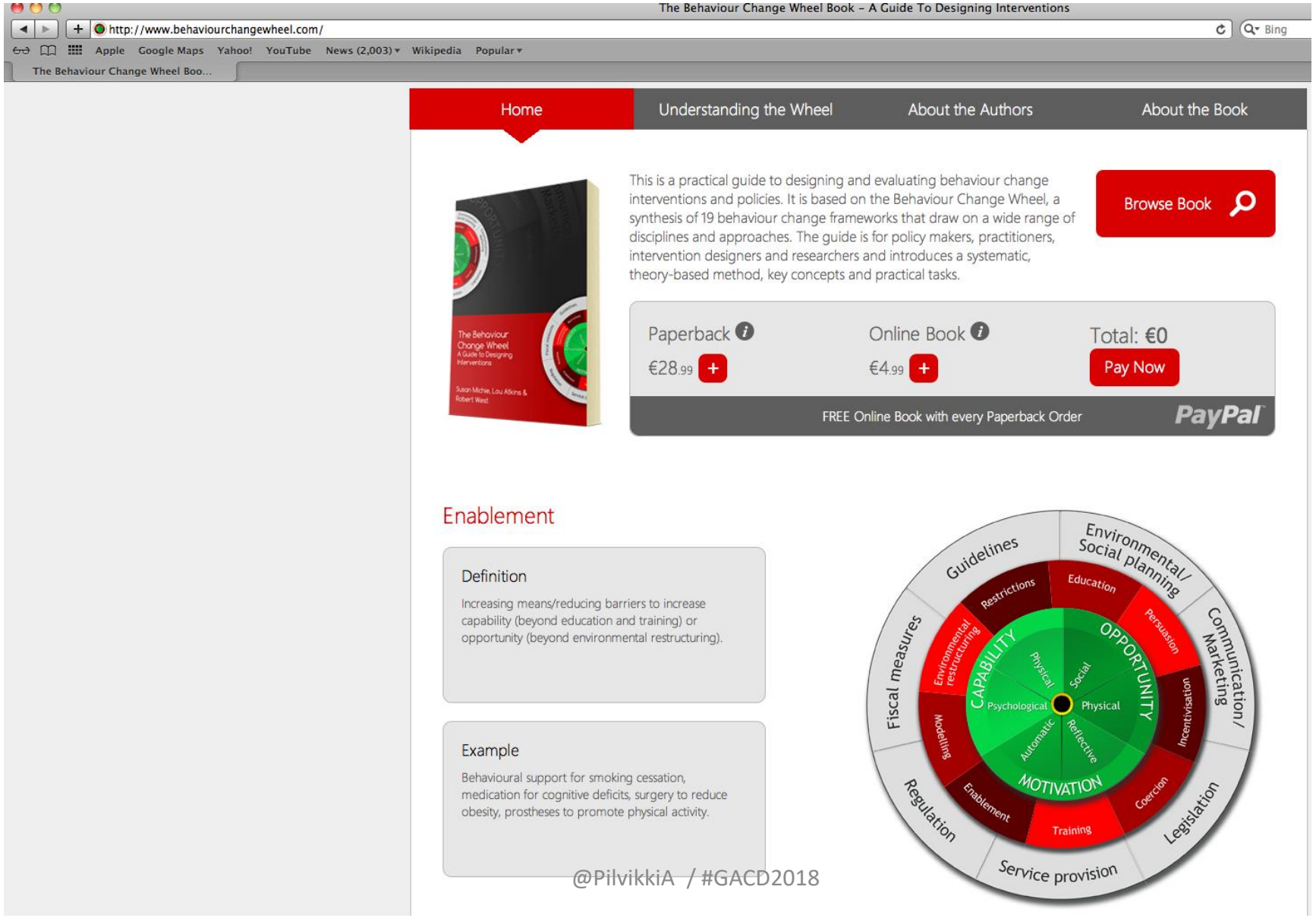
Conscious and automatic processes	Motivation	I don't think it's important , harms outweigh benefits, I don't want, I'm afraid…	INTERVENTION: Motivational interviewing, working with illness perceptions, working with emotions….
Physical Psychological	Capability	I can't, I don't remember…	INTERVENTION: Teaching, showing, planning, habit-automation
Physical and social environment	Opportunity	I can't afford, they're not available, I don't get support…	INTERVENTION: Financial, practical, social support

Only 12% of non-adherence is unvolitional (forgetting), 88 % is volitional

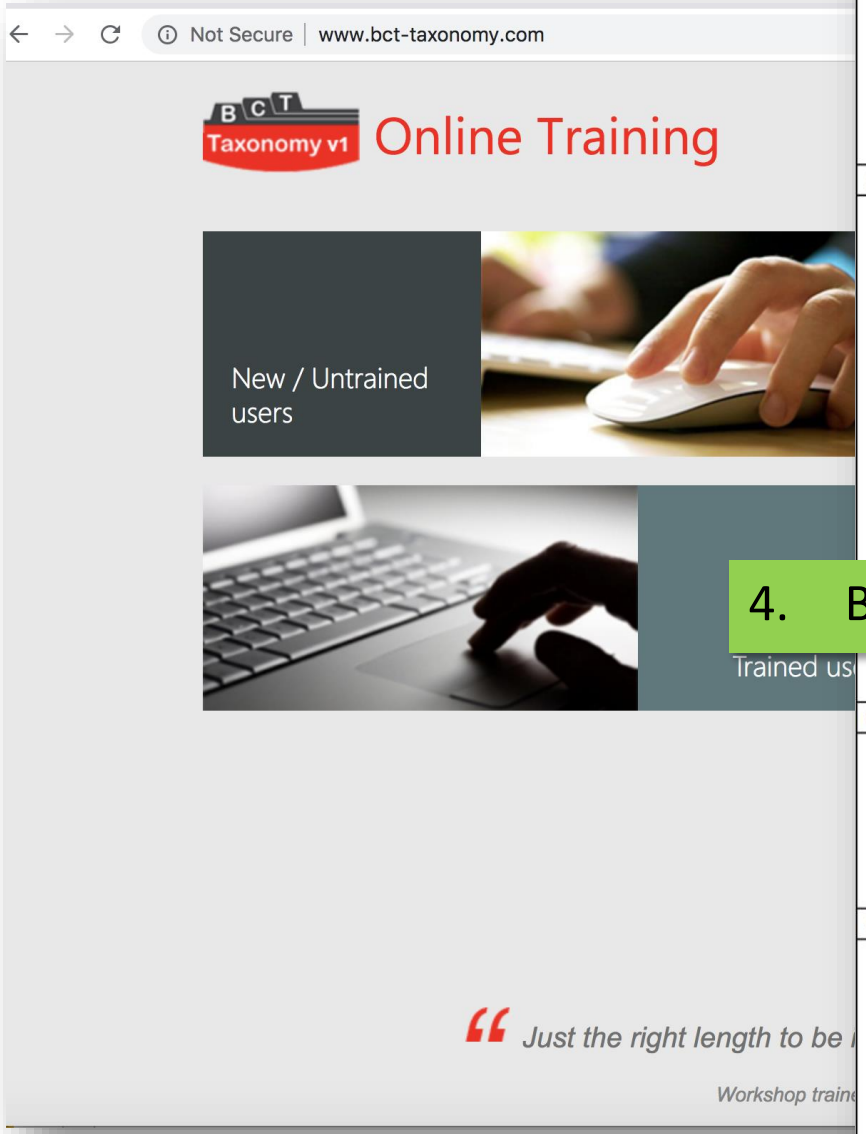
McHorney CA, Spain CV. Frequency of and reasons for medication non-fulfillment and non-persistence among American adults with chronic disease in 2008. Health Expect. 2011;14:307–20.

Michie, S., van Stralen M.M. & West, R. (2011). The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implementation Science, 6, 42.

Behaviour Change Wheel



Behaviour Change I



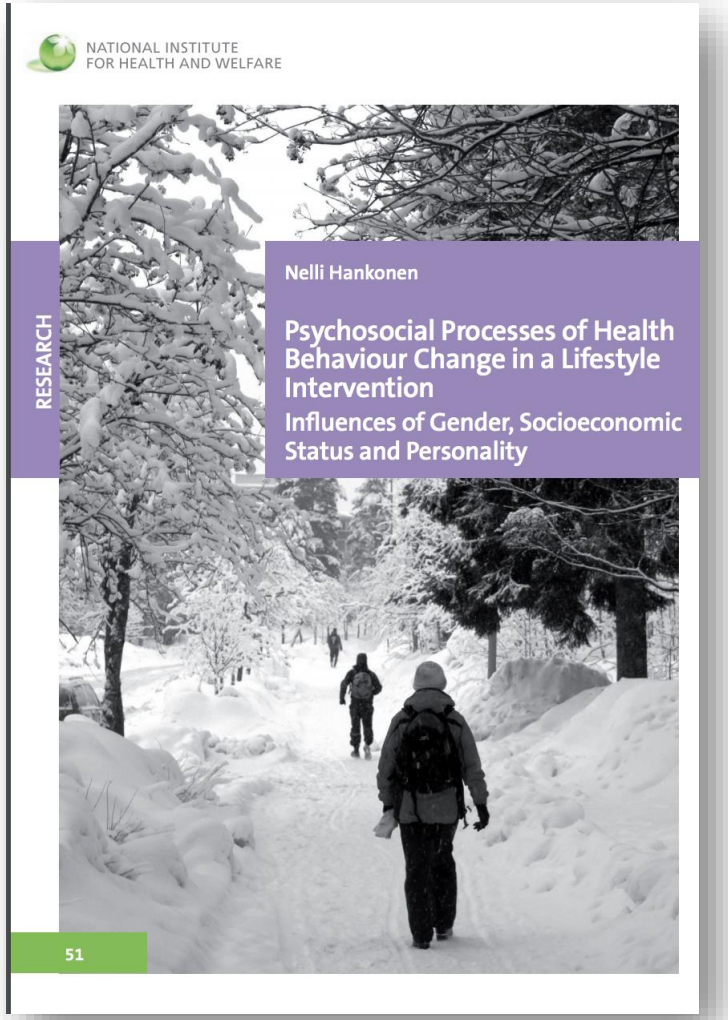
11. Environmental context and resources

- Environmental stressors
- Resources/material resources
- Organisational culture/climate
- Salient events/critical incidents
- Person x environment interaction
- Barriers and facilitators

4. Beliefs about capabilities

- Self-confidence
- Perceived competence
- Self-efficacy
- Perceived behavioural control
- Beliefs
- Self-esteem
- Empowerment
- Professional confidence

Page	Grouping and BCTs
17	**12. Antecedents**
	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
17	**13. Identity**
	13.1. Identification of self as role model
	13.2. Framing/reframing
	13.3. Incompatible beliefs
	13.4. Valued self-identify
	13.5. Identity associated with changed behavior
18	**14. Scheduled consequences**
	14.1. Behavior cost
	14.2. Punishment
	14.3. Remove reward
	14.4. Reward approximation
	14.5. Rewarding completion
	14.6. Situation-specific reward
	14.7. Reward incompatible behavior
	14.8. Reward alternative behavior
	14.9. Reduce reward frequency
	14.10. Remove punishment
19	**15. Self-belief**
	15.1. Verbal persuasion about capability
	15.2. Mental rehearsal of successful performance
	15.3. Focus on past success
	15.4. Self-talk
19	**16. Covert learning**
	16.1. Imaginary punishment
	16.2. Imaginary reward
	16.3. Vicarious consequences



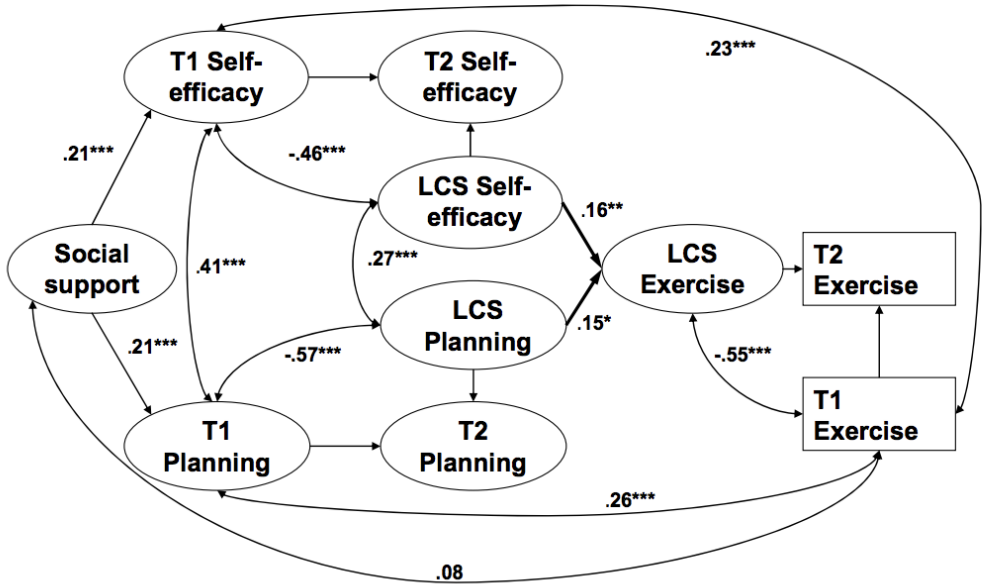
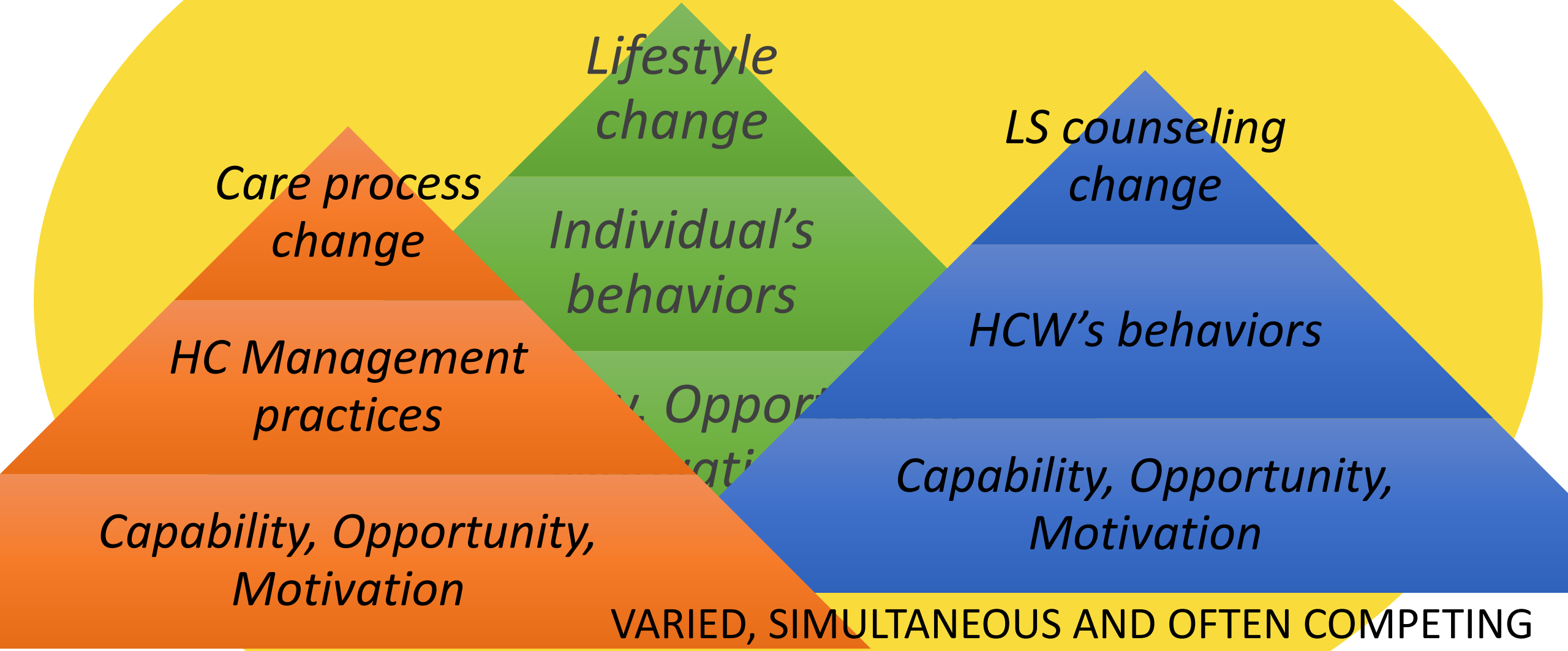


Figure 12: Changes in adoption self-efficacy and action planning as determinants of changes in exercise (Study I).

The overall estimate for the total sample for each parameter is shown. Standardised coefficients. Some of the parameters are excluded for presentation purposes.
T1 = Baseline, T2 = Post-intervention (three months)
*** $p < .001$, ** $p < .01$, * $p < .05$.

https://helda.helsinki.fi/bitstream/handle/10138/24850/psychoso.pdf?sequence=3

REAL-WORLD INTERVENTIONS ARE OFTEN COMPLEX

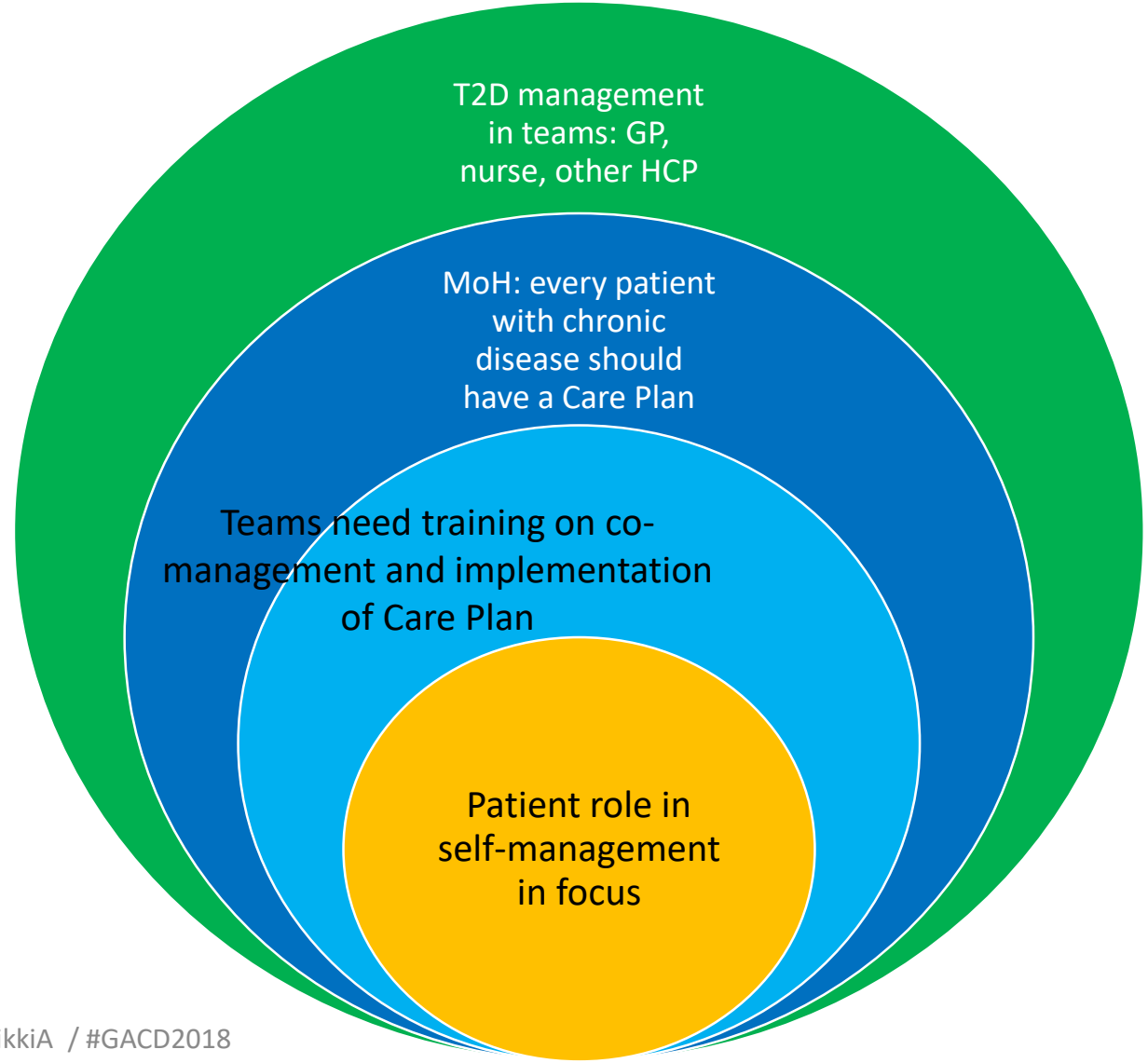


VARIED, SIMULTANEOUS AND OFTEN COMPETING GOALS ON DIFFERENT LEVELS

Example: Implementation without the science

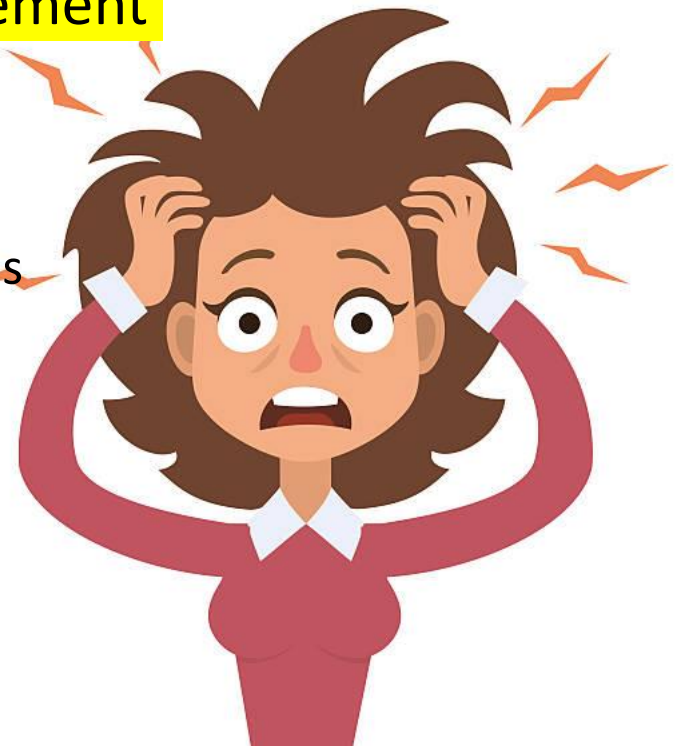
'Giving the driver's seat to the patient'-project:

- Implementation of CSMP with protocol and training for HCP
- All materials were developed in a participatory process with HCP and patients
  - *Patient need and resource questionnaire*;
  - *Lead questions* to guide CSMP discussion
  - Protocol for auditing CSMP individually, one-on-one with a peer mentor, and in groups
  - Guide for managers: How to develop structures to support CSMP
- All PHC had change agents: nurse (+ physician) to inform, facilitate and conduct training



Example c'ed: What happened?

- For change agents at PHC, a steep learning curve, many nurses higly involved and those who were involved were happy about their role
- Patients were satisfied, felt more secure in disease management
- Emergency visits decreased 50%



BUT:

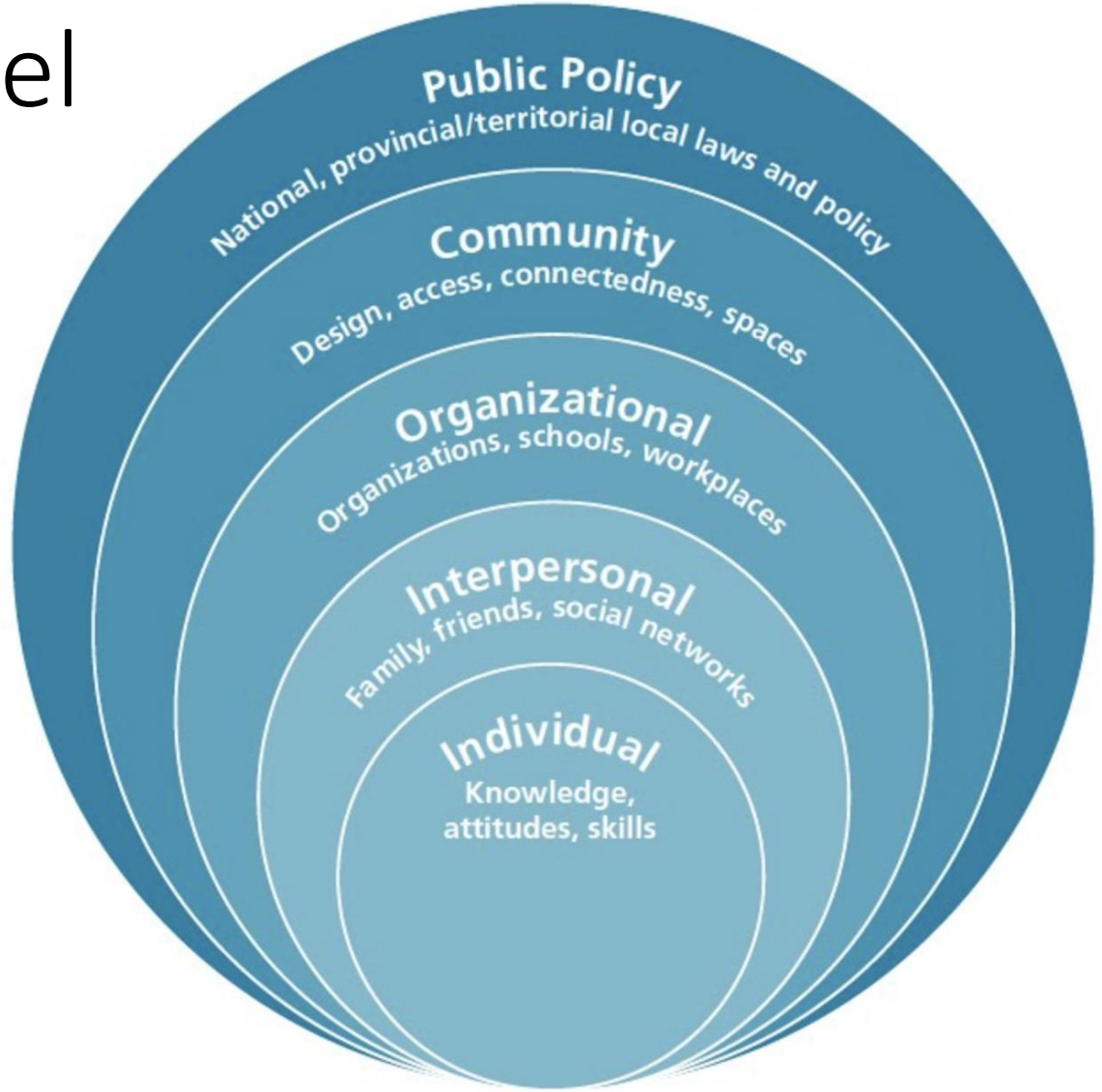
- Many doctors did not prioritize CSMP and did not accept the new roles
- Managers to HCP: "You don't have to do this if you don't have the time"

→ Failure of sustained implementation and scale up

WHY?

- Need for implementation RESEARCH and THEORY
- Sufficient actions targeting the right determinants on ALL the appropriate levels

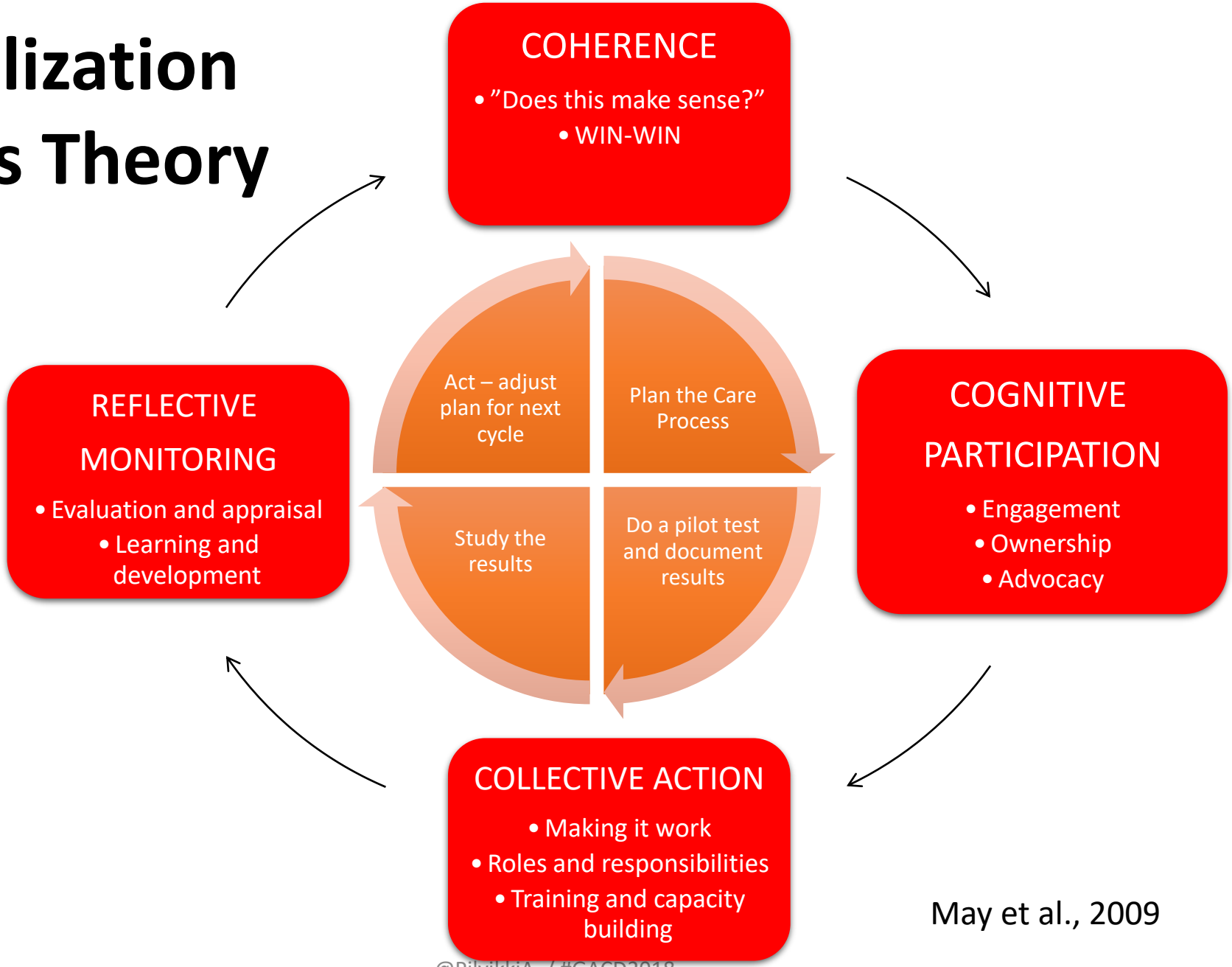
Social-Ecological Model



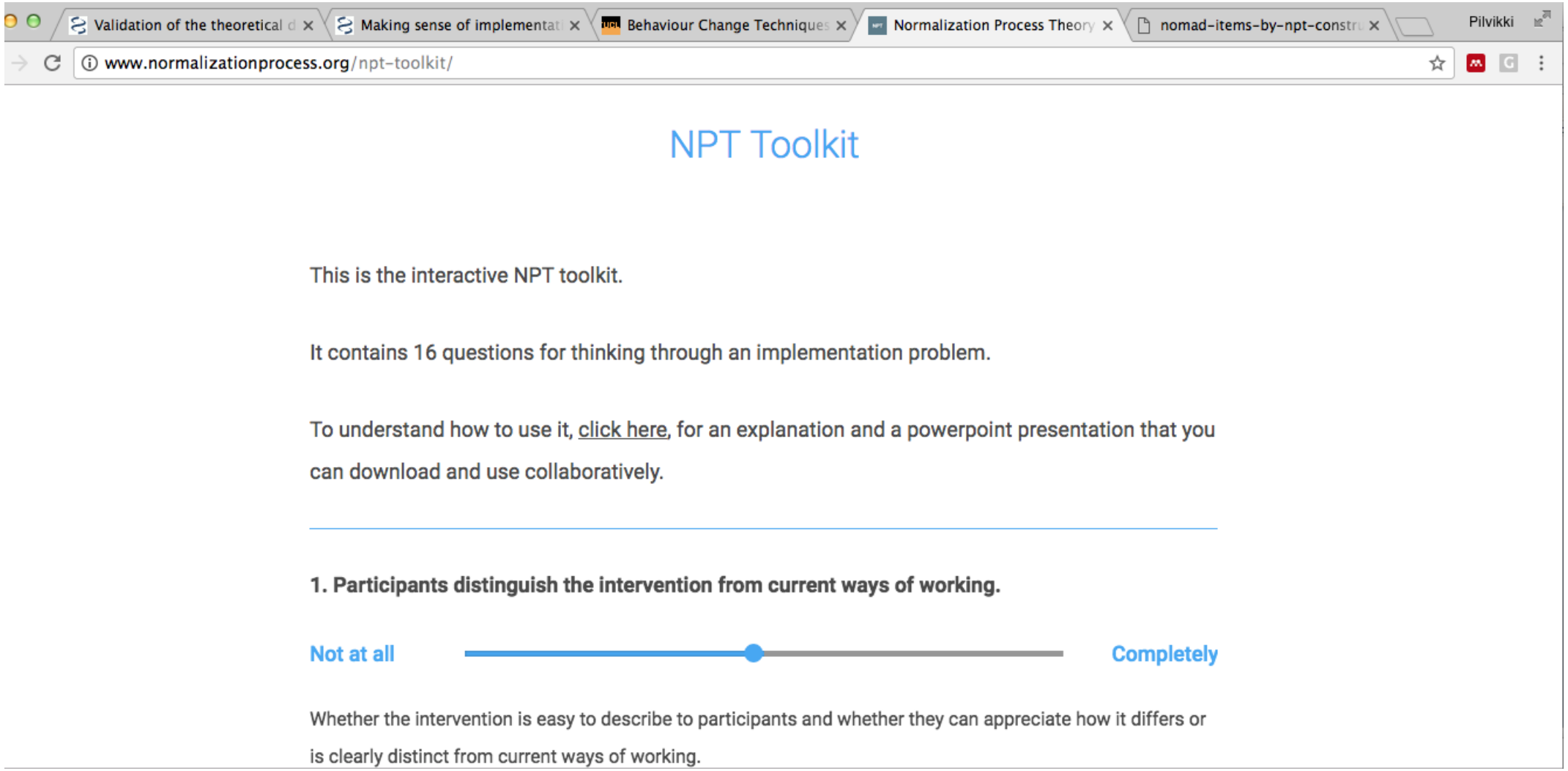
A Social-Ecological Model for Physical Activity - Adapted from Heise, L., Ellsberg, M., & Gottemoeller, M. (1999)

Adaptation by Active Canada 2020

Normalization Process Theory



May et al., 2009


Validation of the theoretical d
Making sense of implementati
Behaviour Change Techniques
Normalization Process Theory
nomad-items-by-npt-constru
Pilvikki
www.normalizationprocess.org/npt-toolkit/
NPT Toolkit
This is the interactive NPT toolkit.
It contains 16 questions for thinking through an implementation problem.
To understand how to use it, click here, for an explanation and a powerpoint presentation that you can download and use collaboratively.
1. Participants distinguish the intervention from current ways of working.
Not at all
Completely
Whether the intervention is easy to describe to participants and whether they can appreciate how it differs or is clearly distinct from current ways of working.

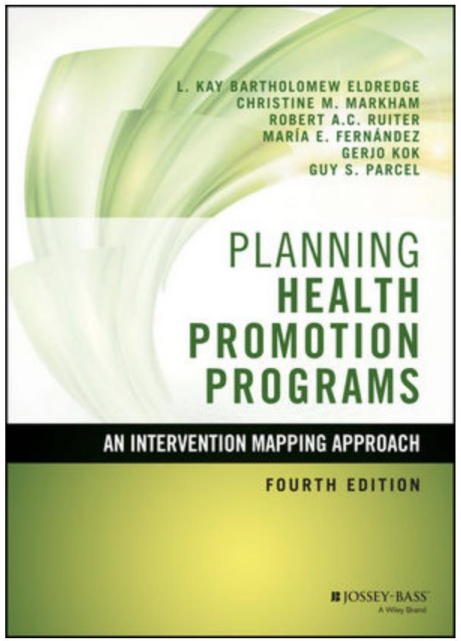
Measure Normalization: NOMAD

NOMAD ITEMS BY CONSTRUCT

Construct	Sub-Construct	Items
Coherence	*Differentiation*	I can see how the [intervention] differs from usual ways of working
	Communal specification	Staff in this organisation have a shared understanding of the purpose of this [intervention]
	Individual specification	I understand how the [intervention] affects the nature of my own work
	Internalization	I can see the potential value of the [intervention] for my work
Cognitive Participation	*Initiation*	There are key people who drive the [intervention] forward and get others involved
	Legitimation	I believe that participating in the [intervention] is a legitimate part of my role
	Enrolment	I'm open to working with colleagues in new ways to use the [intervention]
	Activation	I will continue to support the [intervention]
Collective Action	*Interactional workability*	I can easily integrate the [intervention] into my existing work
	Relational integration	The [intervention] disrupts working relationships
	Relational integration	I have confidence in other people's ability to use the [intervention]
	Skill set workability	Work is assigned to those with skills appropriate to the [intervention]
	Skill set workability	Sufficient training is provided to enable staff to use the [intervention]
	Contextual Integration	Sufficient resources are available to support the [intervention]
	Contextual integration	Management adequately support the [intervention]
Reflexive Monitoring	*Systemisation*	I am aware of reports about the effects of the [intervention]
	Communal appraisal	The staff agree that the [intervention] is worthwhile

http://www.normalizationprocess.org/media/1018/nomad-items-by-npt-construct.pdf

Program objectives	Change objectives	Determinants	Practical strategies
To improve GDM management	Women with elevated glu need to…	COM-B? TDF?	BCT + delivery
	CHW need to…	COM-B? TDF? NPT constructs?	BCT + delivery
	Nurses need to…	COM-B? TDF? NPT constructs?	BCT + delivery
	Physicians need to…	COM-B? TDF? NPT constructs?	BCT + delivery
	Health care organization management needs to…	NPT constructs?	BCT + delivery



The fourth edition of the Intervention Mapping book

Research article | Open Access | Open Peer Review

Developing an implementation strategy for a digital health intervention: an example in routine healthcare

Jamie Ross, Fiona Stevenson, Charlotte Dack, Kingshuk Pal, Carl May, Susan Michie, Maria Barnard and Elizabeth Murray

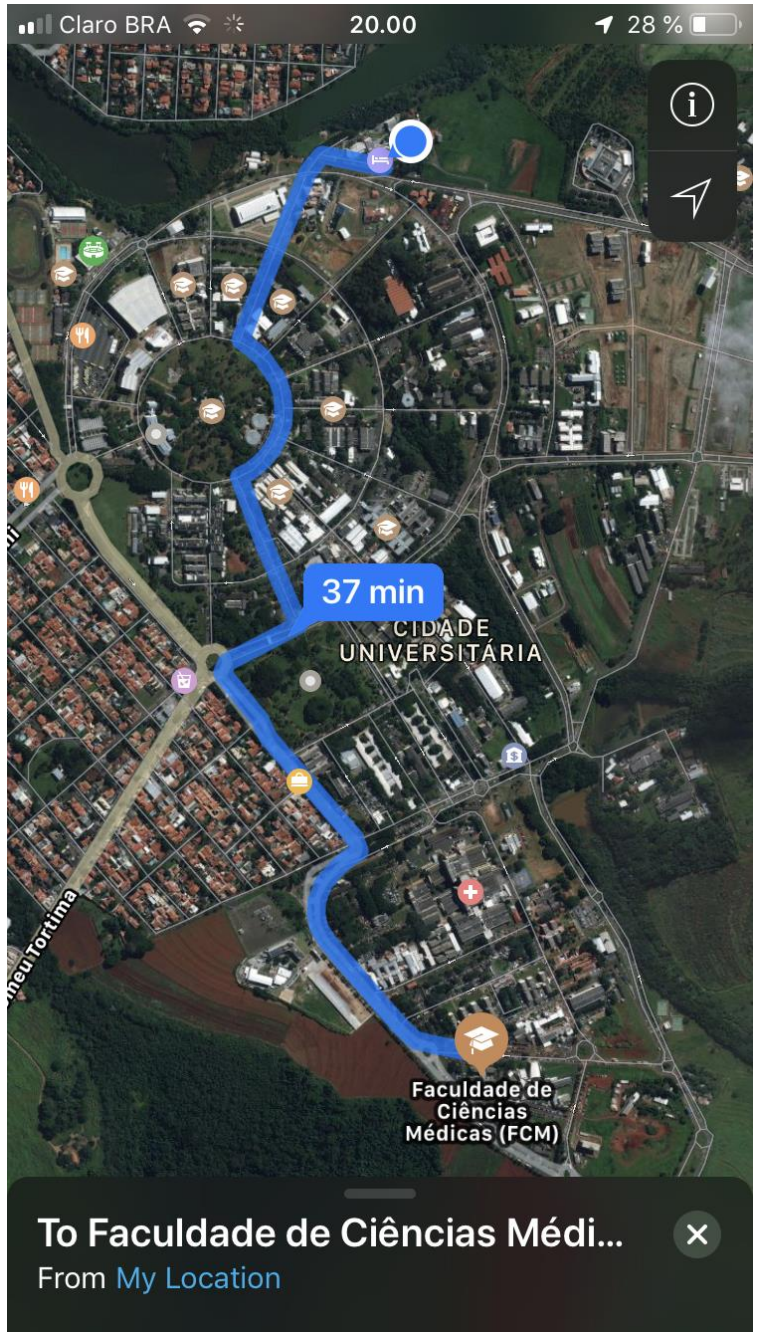
BMC Health Services Research 2018 **18**:794
https://doi.org/10.1186/s12913-018-3615-7
Received: 9 May 2018 | **Accepted:** 9 October 2018 | **Published:** 19 October 2018

Open Peer Review reports

Abstract

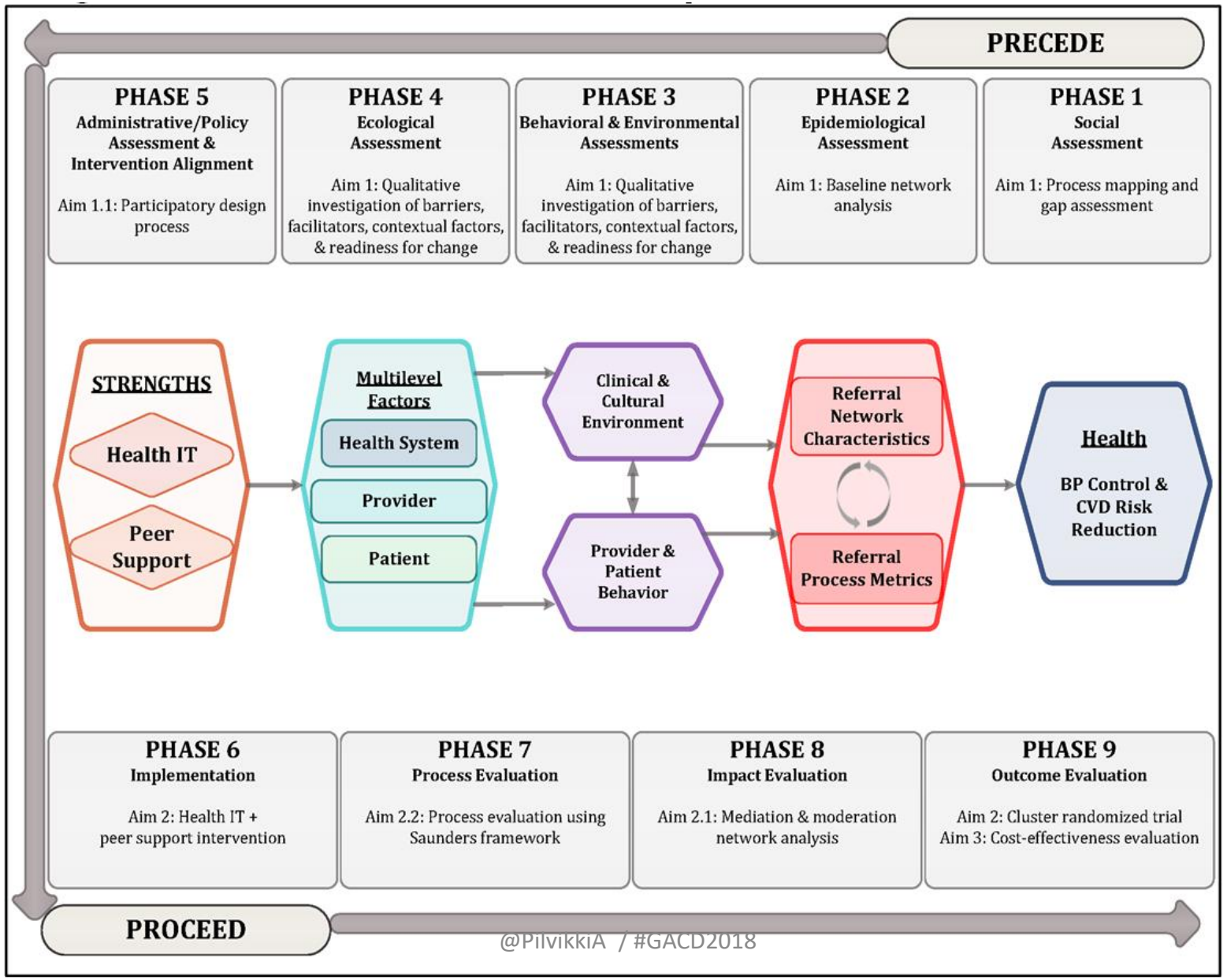
Background

Evidence on how to implement new interventions into complex healthcare environments is often poorly reported and indexed, reducing its potential to inform initiatives to improve healthcare services. Using the implementation of a digital intervention within routine National Health Service (NHS) practice, we



PART 3:
TMF to guide evaluation of implementation – but also useful to consider when planning the implementation

Revisiting Precede-Proceed Model



Mercer et al. Forthcoming

Glasgow RE-AIM framework

Considerations

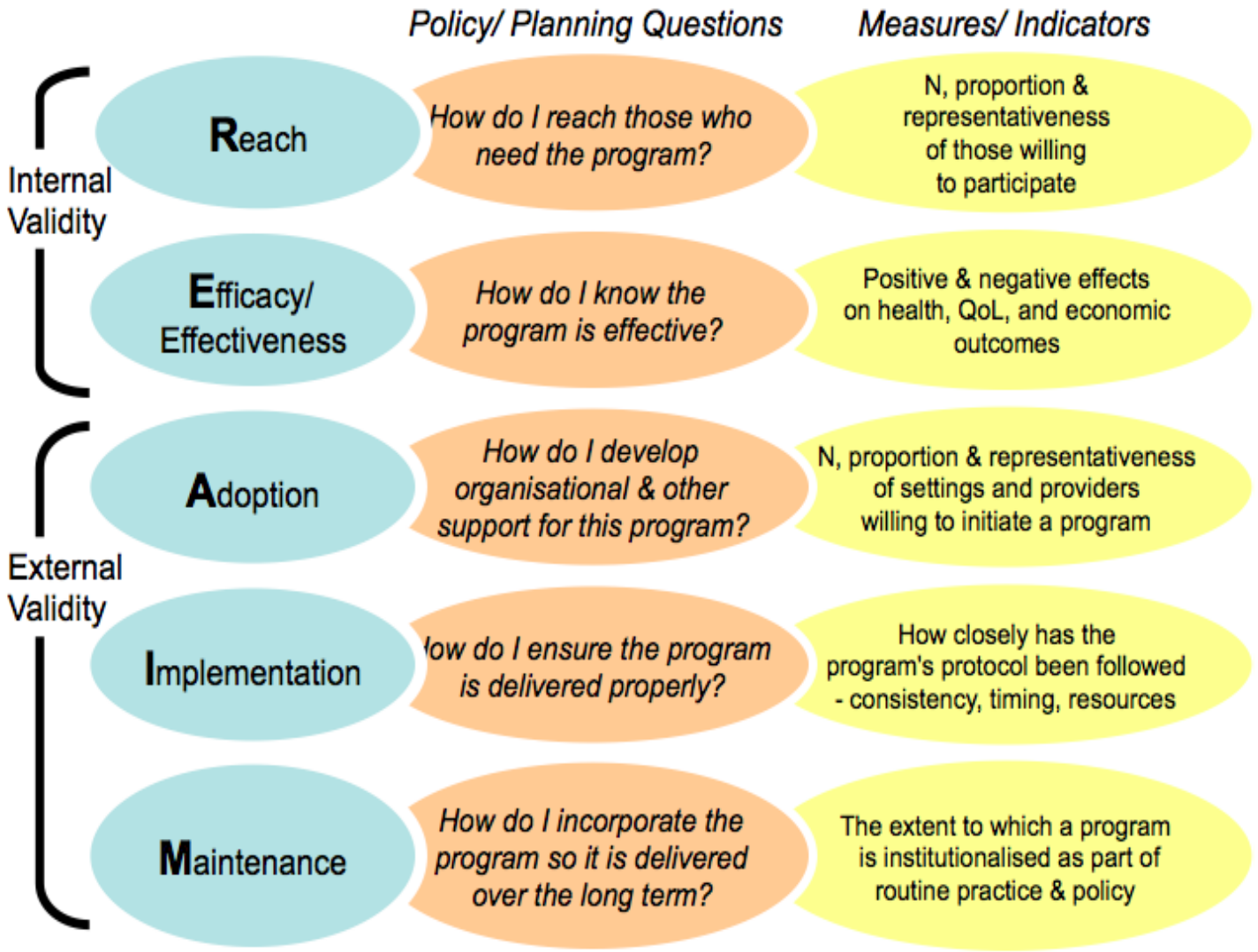
Penetration & participation

Clinical effectiveness BUT also outcomes such as acceptability, adherence

Uptake on all levels

Dose & fidelity

On all levels



Theoretical Framework of Acceptability (TFA)

Affective Attitude	• How an individual feels about the intervention
Burden	• The perceived amount of effort that is required to participate in the intervention
Effectiveness	• The extent to which the intervention is perceived as likely to achieve its purpose
Opportunity Costs	• The extent to which benefits, profits or values must be given up to engage in the intervention
Intervention Coherence	• The extent to which the participant understands the intervention, how it addresses their condition and how it works
Self-efficacy	• The participant's confidence that she can perform the behaviors required to participate in the intervention
Ethicality	• The extent to which the intervention has good fit with an individual's value system

Source: Sekhon et al. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. BMC Health Services Research, 2017. DOI: 10.1186/s12913-017-2031-8


@PiiyikkiA / #GACD2018

What do we mean by "context"?

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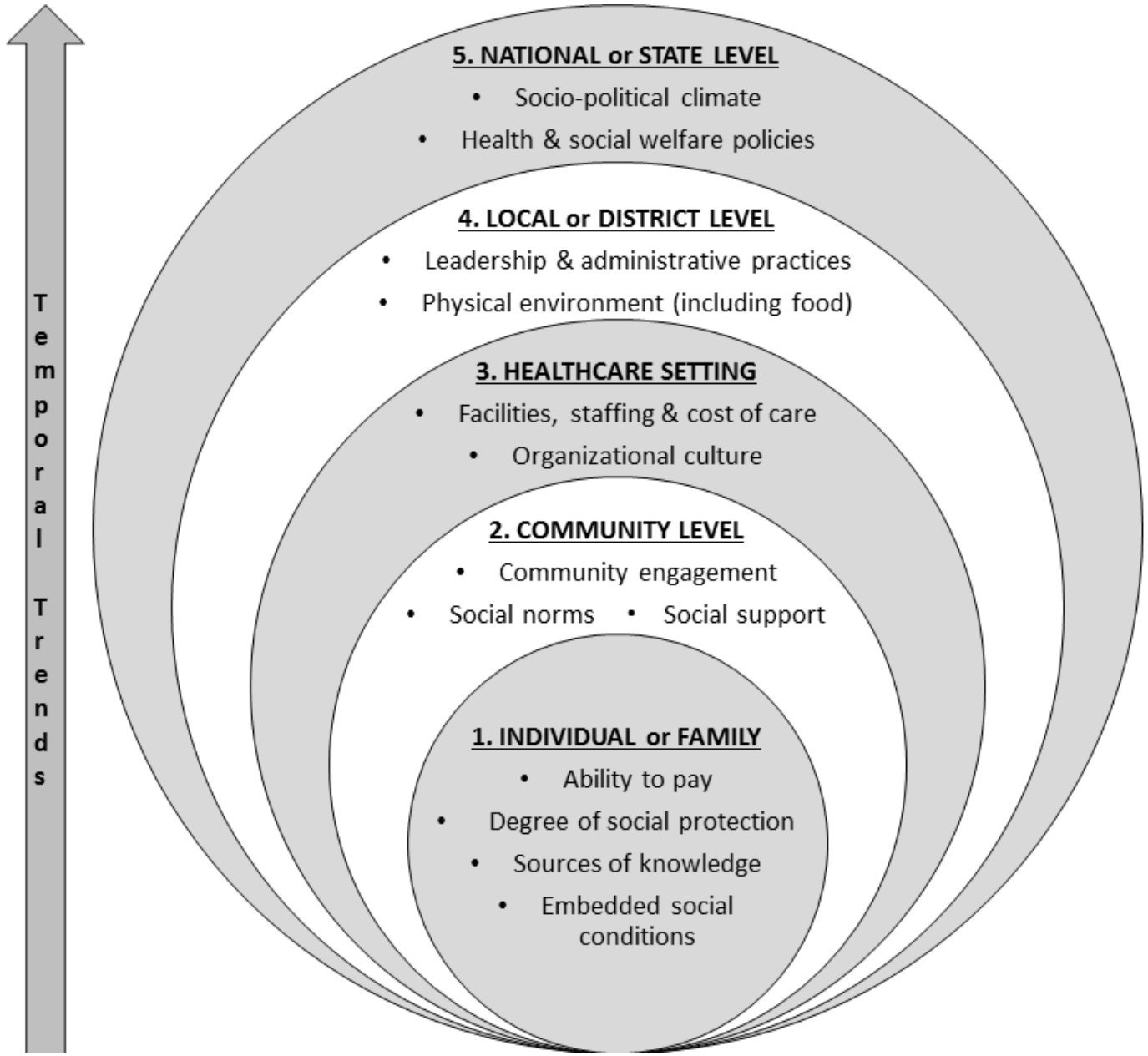

Daivadanam et al., forthcoming

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How do health behavior interventions take account of context? (Holman, Lynch and Reeves, 2017, *Health*)

- Research has focused on the individual level but needs to go back to addressing other levels.

- A more critical reflection is needed:
  - "culture" seems to be the key.
  - Economic and political context are also important.
  - Also poverty, norms, environment.

- A range of disciplines should be involved.

- Qualitative or mixed methods are ideal.

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Value of qualitative methods

- Elicit stakeholder-centered perspectives.
- Inform design and implementation
- Understand contexts across diverse settings
- Provide documentation and encourage reflection on implementation processes
- Gain insight into implementation effectiveness
- Understand mechanisms of change
- Contribute to theoretical development

https://cancercontrol.cancer.gov/IS/docs/NCI-DCCPS-ImplementationScience-WhitePaper.pdf

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Recommendations

- It’s ok to pick a context level and frameworks that you’re not completely in love with, even if you end up making modifications.
- Embrace the “messy”!
- Engage with others who are doing this type of work (and pressure funders and publishers to pay attention).
- Others?

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Effectiveness of lifestyle intervention on incidence of type 2 diabetes in a high-risk population selected using a diabetes risk score in India: a cluster randomized controlled trial

KERALA DIABETES PREVENTION PROGRAM

K R Thankappan, MD, MPH, FAMS (on behalf of KDPP team)
Emeritus Professor, Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, India. Email: kr.thankappan@gmail.com

Introduction

- India has more than 69 million Type 2 diabetics (T2DM).
- Diabetes prevention programs in Finland, USA, and China have demonstrated a reduction in T2DM incidence between 42-58%.
- In India, diabetes prevention trials have primarily targeted those with impaired glucose tolerance or impaired fasting glucose.
- However, in resource-constrained settings, it is not feasible to identify 'high risk' individuals with laboratory testing .

Objectives

To evaluate the effectiveness of a community-based diabetes prevention program on incidence of type 2 diabetes, behavioral, psychosocial, anthropometric, and biochemical measures at 24 months.


INDIA
States and Union Territories
N
TAJIKISTAN
AFGHANISTAN
PAKISTAN
CHINA
NEPAL
BHUTAN
BANGLADESH
MYANMAR
SRI LANKA
INDIAN OCEAN
ARABIAN SEA
BAY OF BENGAL
Srinagar
JAMMU & KASHMIR
Jammu
HIMACHAL PRADESH
Shimla
Chandigarh
PUNJAB
Dehradun
UTTARAKHAND
HARYANA
DELHI
New Delhi
Jaipur
UTTAR PRADESH
Lucknow
RAJASTHAN
SIKKIM
Gangtok
Hanagar
ARUNACHAL PRADESH
Dispur
ASOM (ASSAM)
NAGALAND
Kohima
Shillong
MEGHALAYA
Imphal
MANIPUR
Aizawl
MIZORAM
Agartala
TRIPURA
BIHAR
Patna
JHARKHAND
Ranchi
WEST BENGAL
Kolkata
Gandhinagar
Bhopal
MADHYA PRADESH
GUJARAT
Raipur
CHHATTISGARH
ODISHA (ORISSA)
Bhubaneswar
DAMAN & DIU
Daman
Silvassa
DADRA & NAGAR HAVELI
Mumbai
MAHARASHTRA
Hyderabad
ANDHRA PRADESH
Yanam (Puducherry)
Panaji
GOA
KARNATAKA
Bengaluru (Bangalore)
Chennai
PUDUCHERRY (Pondicherry)
Karaikal (Puducherry)
TAMIL NADU
KERALA
Kavaratti
LAKSHADWEEP (INDIA)
Thiruvananthapuram
Palk Strait
ANDAMAN & NICOBAR ISLANDS (INDIA)
Port Blair
LEGEND
International Boundary
State Boundary
Country Capital
State Capital
Map not to Scale
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This map is updated as on June 12, 2012


KERALA
DISTRICT MAP
N
Kasaragod
KASARAGOD
KARNATAKA
KANNUR
Kannur
WAYANAD
Mahe (Puducherry)
Kalpetta
KOZHIKODE
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TAMILNADU
MALAPPURAM
Malappuram
PALAKKAD
Palakkad
Thrissur
THRISSUR
ERNAKULAM
Ernakulam
IDUKKI
Painavu
KOTTAYAM
Kottayam
Alappuzha
PATHANAMTHITTA
Pathanamthitta
ALAPPUZHA
KOLLAM
Kollam
THIRUVANANTHAPURAM
Thiruvananthapuram
LEGEND
State Boundary
District Boundary
District HQ
State Capital
Map not to Scale
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(Updated on 8th February 2013)


Kollam
Chirayinkeezhu Taluk
Varkala
Attingal
Nedumangad Taluk
Tamil Nadu
Nedumangad
Thiruvananthapuram Taluk
Thiruvananthapuram
Neyyattinkara Taluk
Arabian Sea
Neyyattinkara

Methods

Study design and setting

- The study was a cluster randomized controlled trial.
- Neyyatinkara taluk has 4 Legislative Assembly Constituencies (LACs) and 603 polling booths (PBs).
- 60 PBs were randomly selected.
- Randomized to Lifestyle Intervention arm (30 PBs) or Health Education arm (30 PBs).

Eligibility criteria

Inclusion

- Randomly selected males and females on the electoral roll from the 60 selected PBs. Age - 30-60 years.
- Able to read, write and speak Malayalam (local language).

Exclusion

- Prior diagnosis of
  - ✓ T2DM
  - ✓ myocardial infarction, heart failure
  - ✓ stroke, cancer, epilepsy
  - ✓ arthritis, dementia
  - ✓ glucocorticoids, anti-psychotic drugs and anti-retroviral drugs
- Pregnancy
- T2DM diagnosis at baseline (OGTT).

Data collection

Step 1: Home screening

- From each PB, 80 participants (50 males and 30 females) were approached at their homes by the data collectors.
- A screening questionnaire consisting of eligibility criteria and Indian Diabetes Risk Score (IDRS) were administered.
- Hip and waist circumference were measured.
- If the participant was eligible (based on inclusion and exclusion criteria and IDRS ≥ 60), they are invited to attend a mobile clinic in their community.
- The data collectors recruited 12 males and 10 females per polling booth for attending the mobile clinic.

Step 2: Mobile clinic

- The clinics ran from 6.30 to around 11.30 am on weekends.
- Schools, church halls, *Anganwadi* halls in primary health centres, panchayat halls, and youth clubs were used for conducting clinics.
- Each participant went through different stations in the following order:

  Registration - Pathology - Medical history questionnaire - Blood pressure - Anthropometry - Main questionnaire - Registration

Those with no T2DM following the clinic continue their study participation.

- Those with T2DM following the clinic were excluded from the study and referred to a health care facility.

School


MONASH University
Sree Chitra Tirunal Institute for Medical Sciences and Technology
കേരള പ്രമേഹ പ്രതിരോധ പദ്ധതി
മൊബൈൽ ക്ലിനിക്

Mobile clinic

Produced with consent of the participant

Pathology

Produced with consent of the participant

Blood pressure

Produced with consent of the participant

Questionnaire

Produced with consent of the participant

Table: Measurement domains and survey tools at baseline and 24 months

Variable	Component	Measurement tools/questions
Demographic measures		Age, sex, education, occupation, and monthly household expenditure
Behavioural measures	Physical activity	Global Physical Activity Questionnaire (GPAQ)
	Tobacco use	WHO STEPS question
	Alcohol use	WHO STEPS question
	Diet	Food Frequency Questionnaire (FFQ)

Variable	Component	Measurement tools/questions
Quality of life	Depression	Patient Health Questionnaire (PHQ-9)
	Assessment of quality of life	Short Form-36
Clinical measures		Waist circumference; hip circumference; height; weight blood pressure; body fat
Biochemical measures		2 hr OGTT, HbA1c, lipid profile (Total cholesterol, HDL, LDL, triglycerides), and fibrinogen

Arms

Health Education arm

Participants' Handbook on risk factors, signs, symptoms, complications of diabetes, and diabetics prevention strategies.

Lifestyle Intervention arm

- Intervention Manager
- *Expert panel:* diabetologists, specialists on nutrition, and physical activity
- *Peer leaders:* One male and one female for each group
- Local Resource Persons

Intervention delivery process

Inaugural meeting

- about the program, benefits
- resource materials, handbook, and workbook.

Workbook: self-monitoring of the lifestyle behaviors, goal setting, goal monitoring, and goal review.

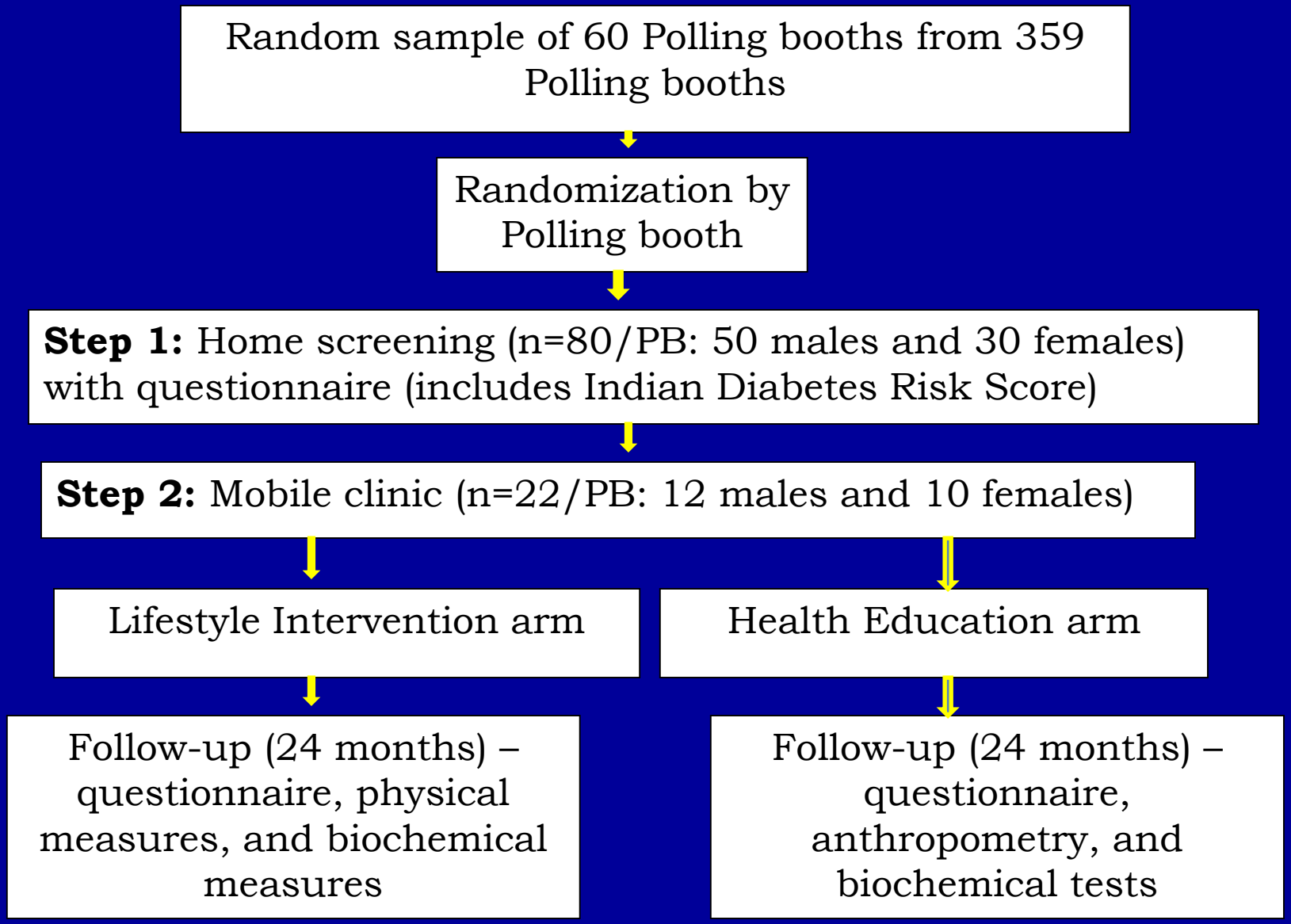
Diabetes prevention education sessions (1 and 2)

- ✓ Understanding of T2DM and its risk factors
- ✓ Prevention strategies
- ✓ Concept of peer support
- ✓ Behaviour change modification

12 small group sessions

- Peer leader led sessions.
- Fortnightly initially, later monthly.
- Group members discuss and share on their behaviors pertaining to diet, physical activity, sleep, alcohol and tobacco use.
- Goal setting, goal monitoring, and review of goals.
- Measuring waist circumference and weight.

Figure: Flowchart of the study



Outcomes

Outcomes	Variables
Primary	
Incidence of T2DM	Fasting Blood Sugar and 2 hr Oral Glucose Tolerance Test (OGTT)
Secondary	
Glycaemic control	Fasting glucose, post load glucose, HbA1C
Lipid profile	Total cholesterol, Triglycerides, HDL, LDL cholesterol
Blood pressure	Systolic and diastolic blood pressure
Obesity	Waist circumference, body mass index, body fat
Behavioural measures	Diet, physical activity, tobacco use, alcohol use
Psychosocial measures	Stress, depression, quality of life, sleep

Data analyses

- Intention to treat analysis.
- Fasting plasma glucose (FPG) at follow-up was compared between arms by Analysis of Covariance (ANCOVA), adjusting for baseline FPG.
- Regression models included adjustment for baseline values of sex, age, family history of diabetes, body mass index, waist circumference, baseline FPG, 2-h OGTT, hypertension, and smoking, when comparing outcomes between arms.

PLOS | MEDICINE

RESEARCH ARTICLE

A peer-support lifestyle intervention for preventing type 2 diabetes in India: A cluster-randomized controlled trial of the Kerala Diabetes Prevention Program

Kavumpurathu R. Thankappan[1☯], Thirunavukkarasu Sathish[2,3☯*], Robyn J. Tapp[2,4], Jonathan E. Shaw[5], Mojtaba Lotfaliany[2], Rory Wolfe[6], Pilvikki Absetz[7,8], Elezebeth Mathews[1,9], Zahra Aziz[2,6,10], Emily D. Williams[11], Edwin B. Fisher[12], Paul Z. Zimmet[5,13], Ajay Mahal[14], Sajitha Balachandran[1], Fabrizio D'Esposito[2], Priyanka Sajeev[1,15], Emma Thomas[2], Brian Oldenburg[2,10]

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☯ These authors contributed equally to this work.
* speaktosat@gmail.com

OPEN ACCESS

Citation: Thankappan KR, Sathish T, Tapp RJ, Shaw JE, Lotfaliany M, Wolfe R, et al. (2018) A peer-support lifestyle intervention for preventing type 2 diabetes in India: A cluster-randomized controlled trial of the Kerala Diabetes Prevention Program. PLoS Med 15(6): e1002575. https://doi.org/10.1371/journal.pmed.1002575

Academic Editor: Ed Gregg, Centers for Disease Control and Prevention, UNITED STATES

Abstract

MAJOR FINDINGS

- **After a median follow-up of 24 months**

  diabetes developed in 17.1% of control participants and 14.9% of intervention participants (p = 0.36).

  The incidence of diabetes in the IGT (Impaired Glucose Tolerance) subgroup was significantly lower in the intervention group (p=0.038)

  Compared with the control group, intervention participants had a ` greater reduction in

  IDRS score (p = 0.022)

  alcohol use (p = 0.018)

  A greater increase

  in fruit and vegetable intake (p = 0.008)

  physical functioning score of the HRQOL scale (p = 0.016)

Kerala Diabetes Prevention Program

A collaborative community based program of Sree Chitra Tirunal Institute and the Kerala Kudumbasree Mission

Objective

- The development of a program delivery model for diabetes prevention and related capacity building in the Indian state of Kerala that can be “scaled up” to rest of India in the future
- Significant improvements in behavioral risk factors – including alcohol consumption, use of tobacco, physical activity and diet – that have already been demonstrated to reduce diabetes progression and incidence in previously conducted efficacy trials

Target group

- Up to 375,000 individuals aged 18+ or older, from 3 geographically distinct and culturally diverse regions in the Indian state of Kerala: Kollam, Ernakulam and Kannur districts.

- These individuals will be men and women receiving support from KSM and their families.

Intended project results

- 15,000 Peer-Leaders trained in the delivery of KDPP
- KDPP delivered to 375,000 men and women from 15,000 neighbourhoods in 3 regions of Kerala
- No weight gain among program participants over 12 months
- A reduction in waist circumference of at least 2.3 cm over 12 months
- A reduction of those consuming tobacco and/or alcohol by at least 5.5% over 12 months
- At least 50% of participants walking for 30 minutes or more at least 5 times a week
- At least 50% of participants achieving individualised dietary targets set with Peer-Leaders
- Reduced progression towards diabetes based on fasting plasma glucose and oral glucose tolerance test (in a subset of 300 individuals)

Thank You

CASE Study: Cultural Translation of T2D Prevention

Pilvikki Absetz, PhD,

CEO, Collaborative Care Systems Finland

Research Director, University of Eastern Finland, Department of Public Health and Clinical Nutrition

Adjunct Professor of Health Promotion, University of Tampere, Faculty of Social Sciences

Kerala Diabetes Prevention Program Team in India

KDPP Indian team in Achutha Menon Centre for Health Sciences,
Sree Chitra Institute of Medical Sciences and Technology

Year 2001: Type 2 Diabetes Recognized as a Global Health Problem

- Diabetes is the fourth leading cause of diseas
- Over 285 million people worldwide are affe
  increase to 438 million by 2030.
- Over 70% of people with T2DM live in LM
  world's diabetes care-related expenditure

- The Finnish Diabetes Prevention Study (Fin- DPS)[1]:
  - Lifestyle modification prevents T2D
- US-DPP and some other prevention trials[2]:
  - Lifestyle modification even more effective than drug treatment
- Da-Qing in China, IDPP
- T2D
- Japanese Prevention Trial[3]:
- d despite small overall changes in

But how to replicate trials in real world?

- Resource-intensive, unrealistic for implementation in routine health care as such
- High-income countries struggle with increasing health care expenditure with aging population and stagnant economies
- Burden in middle- and low-income countries is even higher, but they lack both the infrastructure and the resources

[1]Tuomilehto ym. (2001). Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. New England Journal of Medicine, 344, 1343-1350.

[2]Knowler ym. (2002). Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. New England Journal of Medicine, 346, 393-403

[3]Pan et al., 1997, Ramachandran et al., 2006, Kosaka et al., 2005

Clinical Care/Education/Nutrition/Psychosocial Research
BRIEF REPORT

Type 2 Diabetes Prevention in the World

Three-year results of the GOAL Lifestyle Implementation Tri

Pilvikki Absetz, phd[1]
Brian Oldenburg, phd[2]
Nelli Hankonen, msocsci[1]
Raisa Valve, phd[3]
Heikki Heinonen, phd[1]
Aulikki Nissinen, md, phd[1]
Mikael Fogelholm, scd[4]
Martti Talja, md, phd[5]
Antti Uutela, phd[1]

OBJECTIVE — We study the effectiveness of the GOAL Lifestyle Implementation Trial at the 36-month follow-up.

RESEARCH DESIGN AND METHODS — Participants (n = 352, type 2 diabetes risk score FINDRISC = 16.2 ± 3.3, BMI 32.6 ± 5.0 kg/m^2) received six lifestyle counseling sessions over 8 months. Measurements were at baseline, 12 months (88.6%), and 36 months (77.0%).

RESULTS — Statistically significant risk reduction at 12 months was maintained at 36 months in weight (−1.0 ± 5.6 kg), BMI (−0.5 ± 2.1 kg/m^2), and serum total cholesterol (−0.4 ± 1.1 mmol/l).

CONCLUSIONS — Maintenance of risk reduction in this "real world" trial proves the intervention's potential for significant public health impact.

Diabetes Care 32:1418–1420, 2009

The Goal Lifestyle Implementation Trial (1,2) replicated most of the findings from the Finnish Diabetes Prevention Study (DPS) (3,4) in primary health care settings, demonstrating that lifestyle counseling can be effective and feasible in routine care. We report findings on sustainability of the results at 3 years.

RESEARCH DESIGN AND METHODS — This study was developed and evaluated as a "real world" implementation trial (5). We analyze risk factor changes from baseline to 3-year follow-up.

The intervention, with lifestyle change objectives drawn from the DPS (3), was delivered as six sessions of task-

period of 8 months. The protocol included no other formal postintervention contact with the participants, except follow-up measurements at years 1 and 3.

A fully detailed description of the program content, recruitment, participant characteristics, and measures has been published previously (1). The study sample consisted of 352 participants (age 50–65 years, type 2 diabetes risk assessed by mean FINDRISC [6] score 16.2 ± 3.3), of whom 312 (88.6%) attended the measurements at year 1 and 271 (77.0%) at year 3. Eight participants responded at year 3 but not at year 1.

All clinical data at baseline, and years 1 and 3, were collected by study

tionnaire. Outc
tor changes fro
3 (Table 1). La
were made and
care centers us
ogy as at year 1
Differences
those lost to f
with χ^2 tests ar
tests, risk factor
years 1 and 3 w
and the effect
cholesterol ch
measures ANO
performed using the SPSS for Windows version 15.0.

Principles of the Declaration of Helsinki were followed. The ethics committee of Päijät-Häme Central Hospital reviewed the study protocol. All participants gave their informed consent for the study.

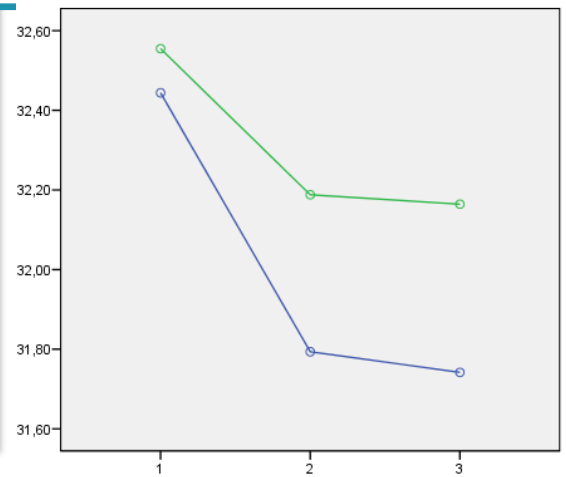
RESULTS — Reduction in weight and BMI achieved by year 1 were maintained also at year 3 (Table 1). Improvement in blood lipids at year 3 was more pronounced than at year 1, but this was mainly attributed to the use of lipid-lowering medication (F = 63.135, P < 0.001 for medication use × total cholesterol interaction). Of the 193 participants with normal glucose tolerance at baseline, 10.9% had impaired glucose tolerance (IGT) and 1.6% had diabetes at year 3. Of the 65 participants who had had IGT at baseline, 12% had diabetes and 43% had returned to normal by year 3.

Participants who completed the study (n = 271) differed from partici-

Attainment of lifestyle change objectives at 1 year:	Fin-DPS % (N=265)	GOAL % (N=352)
Total fat < 30 E %	47	48
Saturated fat< 10 E %	26	34
Fibre > 15g/1000 kcal	25	52
Physical activity > 30 min/day	86	66
Weight loss> 5%	43	12
4-5 objectives met	18	20

N=65 IGT at baseline

- At 3-yr follow-up 43% glucose tolerance back to normal and 12% DM2



Daivadanam M *et al. BMC Public Health* 2013, **13**:95
http://www.biomedcentral.com/1471-2458/13/95

BMC Public Health

RESEARCH ARTICLE **Open Access**

Lifestyle change in Kerala, India: needs assessment and planning for a community-based diabetes prevention trial

Meena Daivadanam[1,2*], Pilvikki Absetz[3], Thirunavukkarasu Sathish[4], K R Thankappan[1], Edwin B Fisher[5], Neena Elezebeth Philip[1], Elezebeth Mathews[1] and Brian Oldenburg[4]

Abstract

Background: Type 2 Diabetes Mellitus (T2DM) has become a major public health challenge in India. Factors relevant to the development and implementation of diabetes prevention programmes in resource-constrained countries, such as India, have been under-studied. The purpose of this study is to describe the findings from research aimed at informing the development and evaluation of a Diabetes Prevention Programme in Kerala, India (K-DPP).

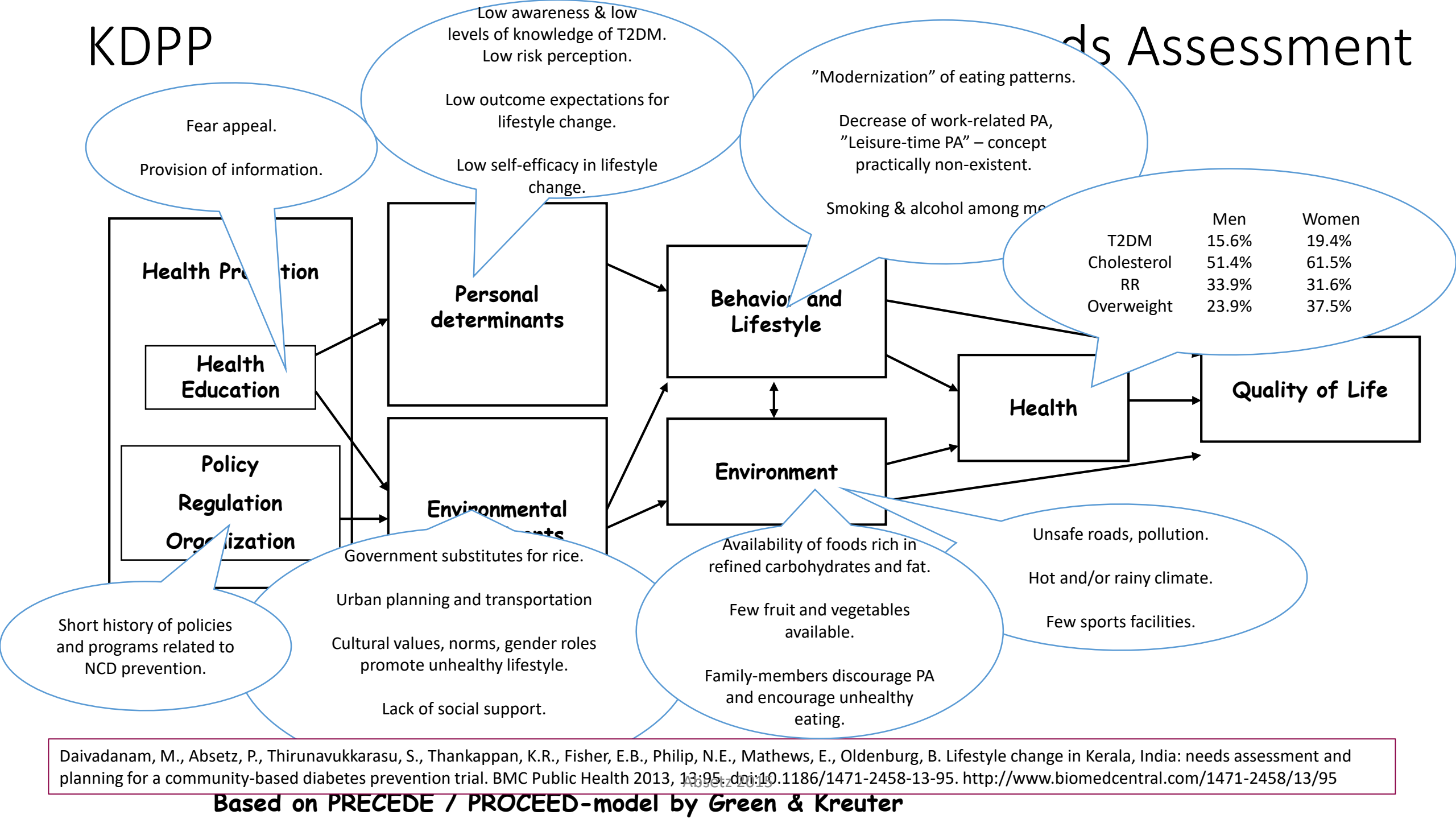
Methods: Data were collected from three main sources: (1) a systematic review of key research literature; (2) a review of relevant policy documents; and (3) focus groups conducted among individuals with a high risk of progressing to diabetes. The key findings were then triangulated and synthesised.

Results: Prevalence of risk factors for diabetes is very high and increasing in Kerala. This situation is largely attributable to rapid changes in the lifestyle of people living in this state of India. The findings from the systematic review and focus groups identified many environmental and personal determinants of these unhealthy lifestyle changes, including: less than ideal accessibility to and availability of health services; cultural values and norms; optimistic bias and other misconceptions related to risk; and low expectations regarding one's ability to make lifestyle changes in order to influence health and disease outcomes. On the other hand, there are existing intervention trials conducted in India which suggests that risk reduction is possible. These programmes utilize multi-level strategies including mass media, as well as strategies to enhance community and individual empowerment. India's national programme for the prevention and control of major non-communicable diseases (NCD) also provide a supportive environment for further community-based efforts to prevent diabetes.

Conclusion: These findings provide strong support for undertaking more research into the conduct of community-based diabetes prevention in the rural areas of Kerala. We aim to develop, implement and evaluate a group-based peer support programme that will address cultural and family determinants of lifestyle risks, including family decision-making regarding adoption of healthy dietary and physical activity patterns. Furthermore, we believe that this approach will be feasible, acceptable and effective in these communities; with the potential for scale-up in other parts of India.

Keywords: Diabetes mellitus, Real world intervention, Diabetes prevention, Pre-diabetes

KDPP ds Assessment



Daivadanam, M., Absetz, P., Thirunavukkarasu, S., Thankappan, K.R., Fisher, E.B., Philip, N.E., Mathews, E., Oldenburg, B. Lifestyle change in Kerala, India: needs assessment and planning for a community-based diabetes prevention trial. BMC Public Health 2013, 13:95. doi:10.1186/1471-2458-13-95. http://www.biomedcentral.com/1471-2458/13/95

Absetz 2015

Based on PRECEDE / PROCEED-model by Green & Kreuter

India: Perceptions on diet

- A protruding belly speaks of a life of embodied satisfaction – good social relationships, status, success and health
- Dietary habits not within individual control.
- Even amidst worry about health and recognition of the risks of unhealthy eating:
  - refusing food would be seen as an expression of anger or annoyance, or as a sign of illness.
  - taking medicines (. . .) is palatable because it doesn't disrupt the flow of food, care, love and pleasure in the households

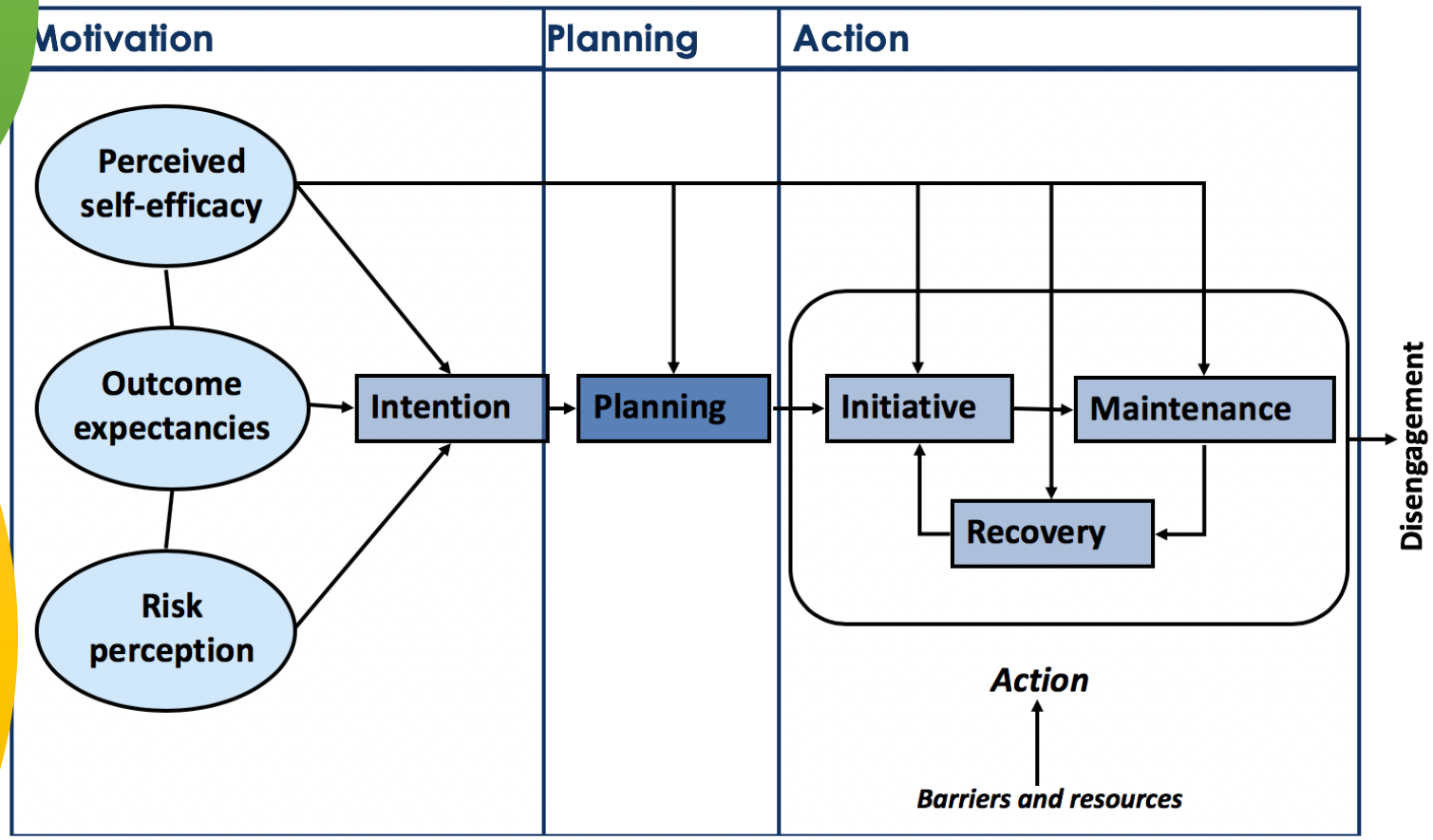
Daivadanam M et al. BMC Public Health 2013, 13:95

Fruits other than bananas belong to children's diet only

I don't believe in any of this. I don't feel I have any risk. I still need double sugar in my tea

I don't think it is possible to make modifications in our lifestyle. No matter what you say, it will just continue like this.

Health Action Process Approach



Schwarzer, R., Fuchs, R. (1996). Self-efficacy and health behaviors. In M. Conner & P. Norman (eds.): Predicting health behaviour: Research and practice with social cognition models (pp. 163-196). Buckingham, UK: Open University Press.

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DOI 10.1186/s12889-017-4986-0

BMC Public Health

RESEARCH ARTICLE Open Access

Cultural adaptation of a peer-led lifestyle intervention program for diabetes prevention in India: the Kerala diabetes prevention program (K-DPP)

Elezebeth Mathews[1,2†], Emma Thomas[3*†], Pilvikki Absetz[4,5,6], Fabrizio D'Esposito[3], Zahra Aziz[3], Sajitha Balachandran[1], Meena Daivadanam[7,8], Kavumpurathu Raman Thankappan[1] and Brian Oldenburg[3]

Abstract

Background: Type 2 diabetes mellitus (T2DM) is now one of the leading causes of disease-related deaths globally. India has the world's second largest number of individuals living with diabetes. Lifestyle change has been proven to be an effective means by which to reduce risk of T2DM and a number of "real world" diabetes prevention trials have been undertaken in high income countries. However, systematic efforts to adapt such interventions for T2DM prevention in low- and middle-income countries have been very limited to date. This research-to-action gap is now widely recognised as a major challenge to the prevention and control of diabetes. Reducing the gap is associated with reductions in morbidity and mortality and reduced health care costs. The aim of this article is to describe the adaptation, development and refinement of diabetes prevention programs from the USA, Finland and Australia to the State of Kerala, India.

Methods: The Kerala Diabetes Prevention Program (K-DPP) was adapted to Kerala, India from evidence-based lifestyle interventions implemented in high income countries, namely, Finland, United States and Australia. The adaptation process was undertaken in five phases: 1) needs assessment; 2) formulation of program objectives; 3) program adaptation and development; 4) piloting of the program and its delivery; and 5) program refinement and active implementation.

Results: The resulting program, K-DPP, includes four key components: 1) a group-based peer support program for participants; 2) a peer-leader training and support program for lay people to lead the groups; 3) resource materials; and 4) strategies to stimulate broader community engagement. The systematic approach to adaptation was underpinned by evidence-based behavior change techniques.

Conclusion: K-DPP is the first well evaluated community-based, peer-led diabetes prevention program in India. Future refinement and utilization of this approach will promote translation of K-DPP to other contexts and population groups within India as well as other low- and middle-income countries. This same approach could also be applied more broadly to enable the translation of effective non-communicable disease prevention programs developed in high-income settings to create context-specific evidence in rapidly developing low- and middle-income countries.

Trial registration: Australia and New Zealand Clinical Trials Registry: ACTRN12611000262909. Registered 10 March 2011.

Keywords: Cultural adaptation, Diabetes prevention, Type 2 diabetes mellitus (T2DM), Low and middle income countries (LMICs), Community-based, Peer support, Lifestyle intervention, Implementation

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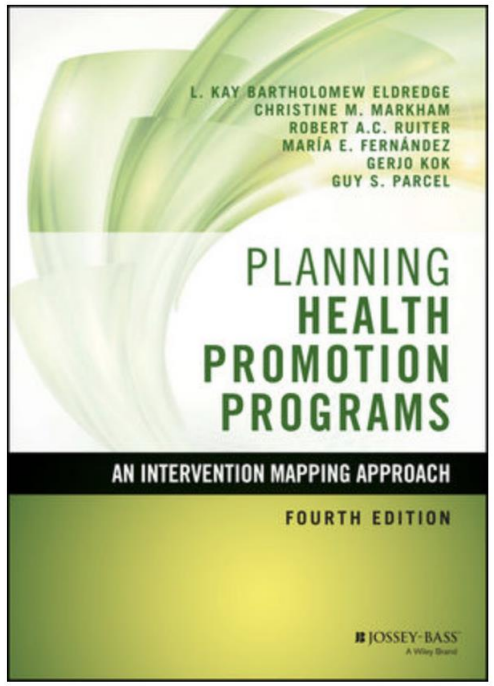


The fourth edition of the Intervention Mapping book

Table 1 Kerala Diabetes Prevention Program objectives, theory-based methods and practical strategies

Program Objectives	Participant learning and environmental change objectives	Theory- and evidence-based determinants as per the Health Action Process Approach [47]	Behavior change techniques as per Michie et al.'s Taxonomy v1 [48] (BCT number)	Feasible and culturally acceptable strategies to enhance engagement and implementation
1. Increase the consumption of fruit, vegetables and fibre 2. Reduce intake of carbohydrates with high glycaemic index and total and saturated fats 3. Increase physical activity 4. Reduce tobacco use with emphasis on chewing tobacco 5. Reduce alcohol consumption, particularly among men 6. Set realistic goals and associated targets for weight loss and other lifestyle risks 7. Improve sleep	Participant learning objective • Increase awareness of the risk factors of T2DM • Improve risk perception on T2DM • Improve self-efficacy in making lifestyle changes Environmental change objective • Enhance peer support for behavior change • Enhance household / family support for behavior change • Enhance neighborhood and community support • Facilitate opportunities for healthy life style with collaboration at group-community level.	• Outcome expectations • Risk perception • Self-efficacy • Action planning • Coping planning	• Goal setting (behavior) (BCT #1.1), action planning (BCT #1.4) and review of behaviour goal(s) (BCT #1.7) e.g. participants are assisted to set realistic behavioral goals and prompted to detail a plan of how they will achieve it. The goals are reviewed within the sessions. • Instruction on how to perform a behaviour (BCT #4.1) e.g. experts advised and up-skilled participants in yoga classes and kitchen garden development • Information about health consequences (BCT #5.1) e.g. information is provided in the DPES sessions and small group sessions on diabetes and potential complications • Problem solving/coping planning (BCT #1.2) e.g. barriers to physical activity and healthy eating are discussed and planned for throughout the small group sessions • Social support (practical) (BCT #3.2), social support (general) (BCT #3.1), and social support (emotional) (BCT #3.3) e.g. inclusion of family members and peer-based intervention is designed to enhance social support	Individual-level • Educational sessions that focus on 'modifiable' determinants of risk on diabetes • Provide information on the risk factors of T2DM • Sessions scheduled in local neighborhoods (e.g. a reading room or *anganwadi*) according to work, family and other cultural needs of participants • Inclusion of strategies to attract more male participation Interpersonal-level • Group-based delivery/ peer-support • Inclusion of family members in the K-DPP sessions • Provide information on the dietary and physical activity targets for individuals as well as family members • Enabling ongoing peer and social support, with family members and friends of participants • Kitchen gardening training and seeds • Forming of walking groups • Yoga training sessions Community-level • Community mobilization activities • Forming partnerships with community stakeholders and organizations • Clearing of walking paths with peer group and community members

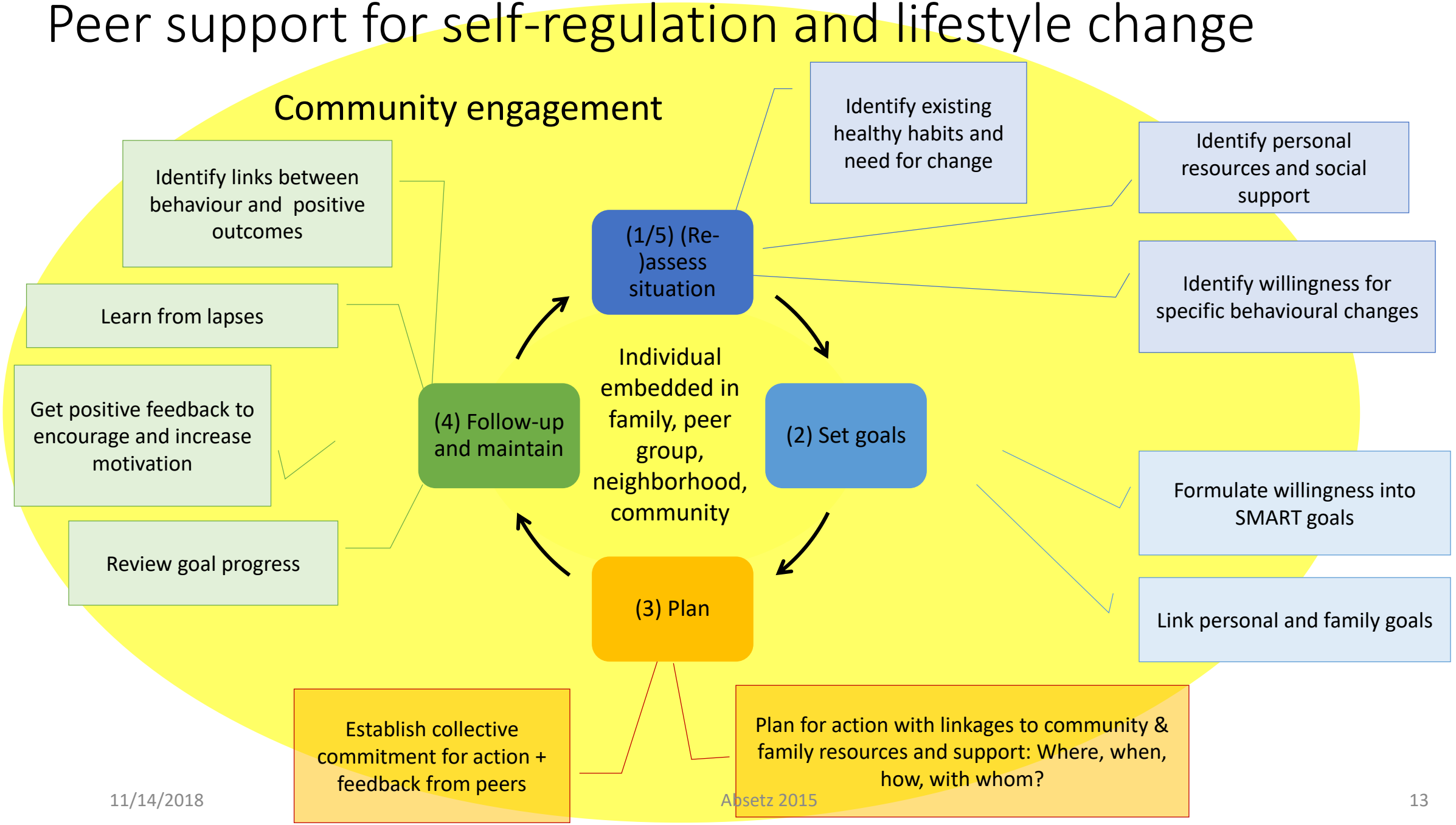
Table 2 Major findings from the pilot phase and modifications made to the Kerala Diabetes Prevention Program

Identified challenge	Strategies adopted	Modifications made
Low education level of the participants. The majority of the participants ($n = 18$) had no formal education, with the highest level of education being 11 years of schooling.	Simplify intervention materials to assist understanding of individuals with lower literacy levels.	Intervention materials were modified with additional pictures to support understanding of text-based information. Additional group-based activities were planned to be incorporated into the sessions to facilitate story-telling and oral language based learning.
Low participation level of male participants.	Recruit male peer-leaders that can encourage male participants to attend. Ensure sessions are run during convenient times for working males.	Male peer-leaders were recruited in addition to the female peer-leaders. Sessions were organised during the evening and on weekends to enhance male participation.
Perceived relevance of T2DM prevention, with priority given to control and management of T2DM	A strong link between prevention and disease management needed to be established to make the program relevant for the participants. Program content (intervention materials and sessions) needed to be modified to sensitize participants on the need for diabetes prevention amongst themselves and their families and to include information on diabetes management. More community awareness on prevention programs was required.	An additional educational session, Diabetes Prevention Education Session (DPES 1), was incorporated into the program. DPES 1 provided an introduction to understanding Type 2 diabetes and its risk factors. This session stressed the similarity of strategies for primary and secondary prevention, and addressed misconceptions and role of lifestyle modification. The original diabetes education session became a sequel to DPES 1. This session, DPES 2, focused on the modifiable risk factors for diabetes prevention. The session took a deeper view on the specifics of healthy lifestyle behaviors, diet, physical inactivity, tobacco and importance of sleep. We also included "Diabetes Management" as an additional topic into the small group sessions to link diabetes management with prevention strategies, and thereby to increase perceived relevance of the program among participants.

Absetz 2017

KDPP Intervention flow

Peer support for self-regulation and lifestyle change



KDPP components and focal areas of influence on different levels by phases of intervention

	Phase I (0-2 mo)	Phase II (2-5 mo)	Phase III (6-12 mo)	Phase IV (12 mo ->)
KDPP Program components	- Recruitment of LRPs - Small group sessions 1-2 - DES I - Peer leader (PL) selection and training I	- Small group sessions 3-5 - Pre- and post-session telephone contact with peer leaders and LRPs - DES II - PL training II	- Small group sessions 6- 12 - Pre- and post-session telephone contact with peer leaders and LRPs - Extra-curricular activities (yoga training , kitchen garden cultivation) - Workshops for PL and LRP and support for planning extra curricular activities in the community (healthy snack preparation, sports meet, painting competition on behaviour change themes)	- Off site support and expertise - Linkage to other services for health care and promotion - Linkage to other community organizations
Peer leader	Selection, commitment	Peer leader skill-building and support for self-efficacy Benefits of being a peer leader	Supporting peer leader self-efficacy, autonomy & perception of benefits Enabling and promoting peer support among peer leaders	Supporting peer leader self-efficacy, autonomy & perception of benefits Promoting linkages with community organizations
Participants (& family)	Recruitment, retention: - Participatory methods - Benefits from participation (participant & family)	Building peer support for and self-efficacy in behaviour change in participant & family	Promoting maintenance of peer support & behaviour change Supporting participants in becoming change agents in their families	Promoting maintenance of peer support & behaviour change in participant & family Supporting participants in becoming change agents in their communities
Community	Increasing community awareness of KDPP and encouraging community support to KDPP	Encouraging community support TO KDPP	How can KDPP groups support health in their communities: extra curricular activities and linkages to community organizations	Support for community roll-out

Note. Regular mentoring meetings with the KDPP team and the advisory team have facilitated progression between the phases

Aziz *et al. Implementation Science* (2018) 13:97
https://doi.org/10.1186/s13012-018-0791-0

Implementation Science

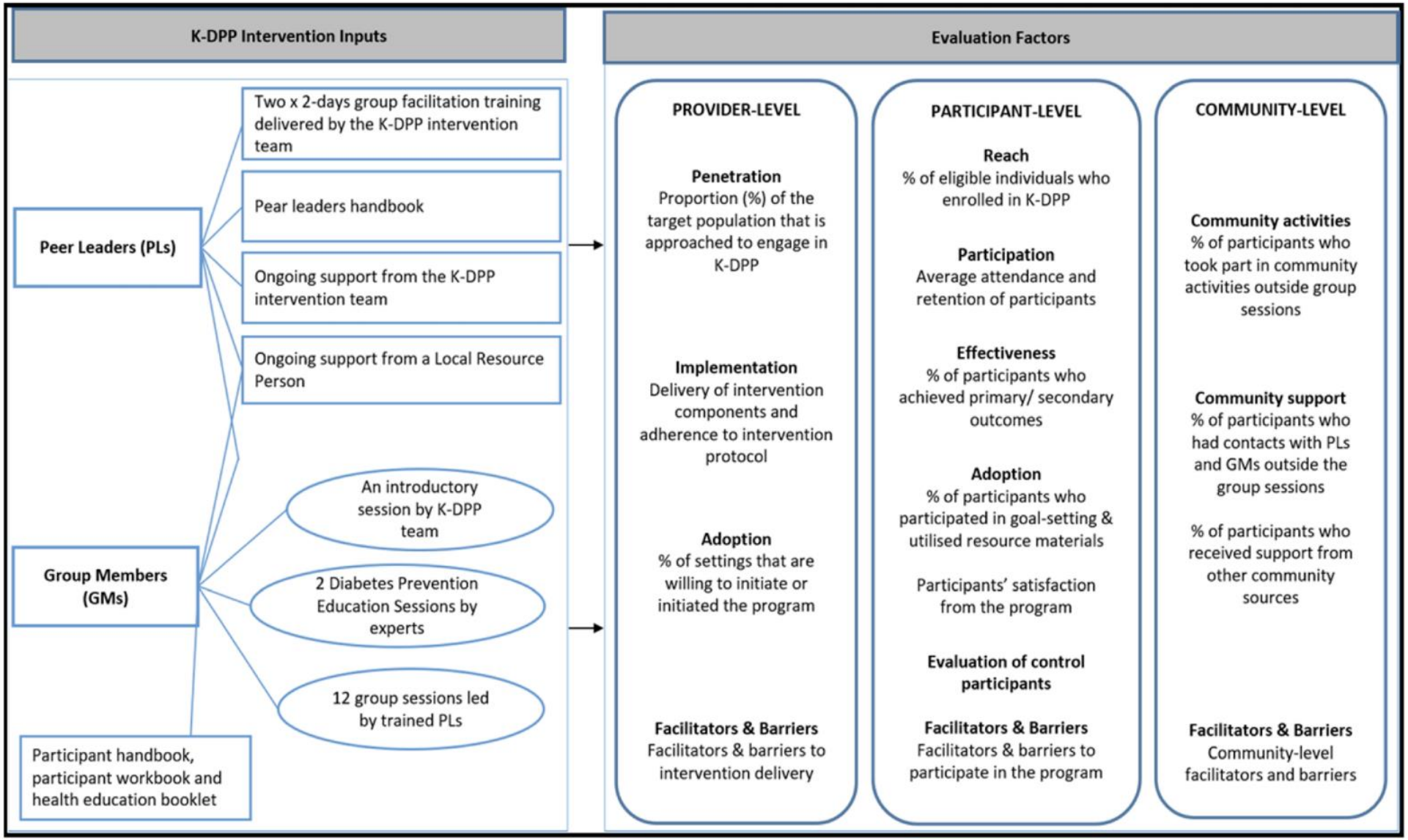
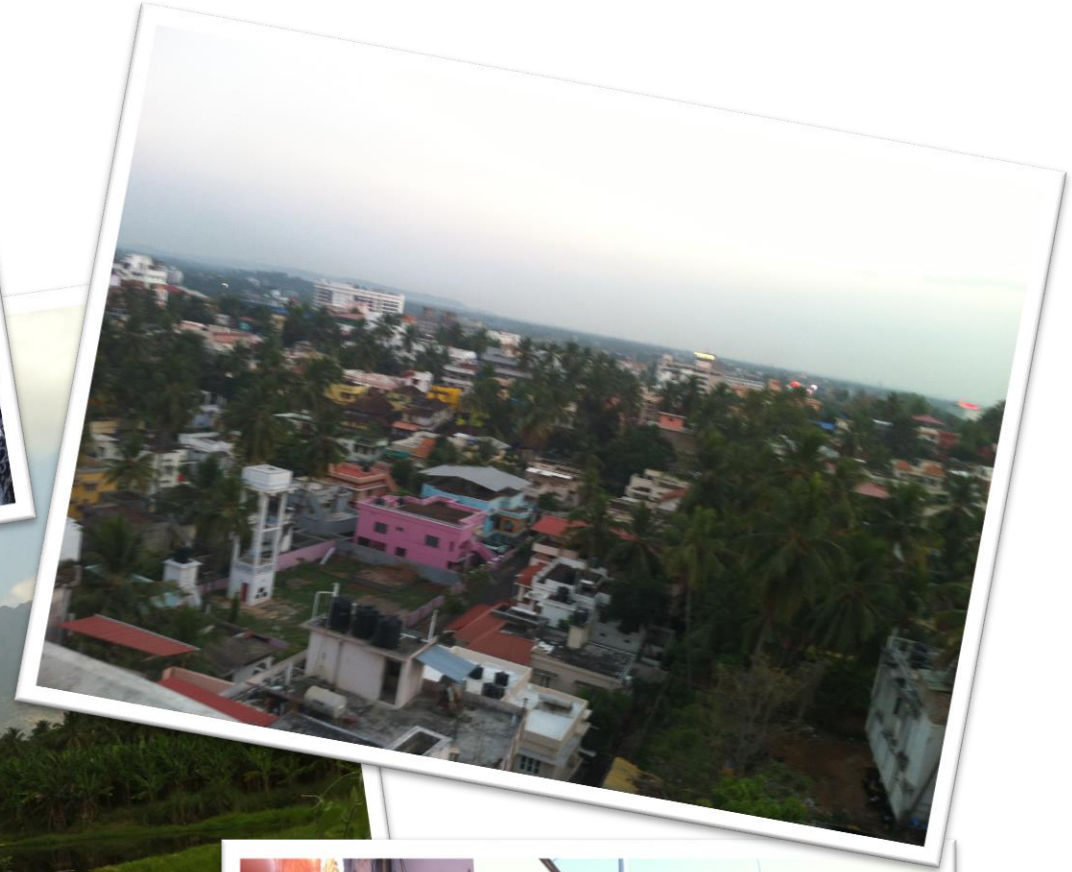


Fig. 1 K-DPP intervention inputs and implementation evaluation factors


CASHEW, BADAM,
PISTA & MASALA



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Implementation Research: Importance of Context

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Director, Section for Global Health
Associate Professor, Departments of Population Health and Medicine
New York University School of Medicine

Disclosures

I receive financial support from the following company or companies related to the products listed below. These relationships may lead to bias in my presentation.

Entity	Type(s) of relationship(s)	Product name(s)	Relevant disease(s) or condition(s)
NONE			

K01TW009218
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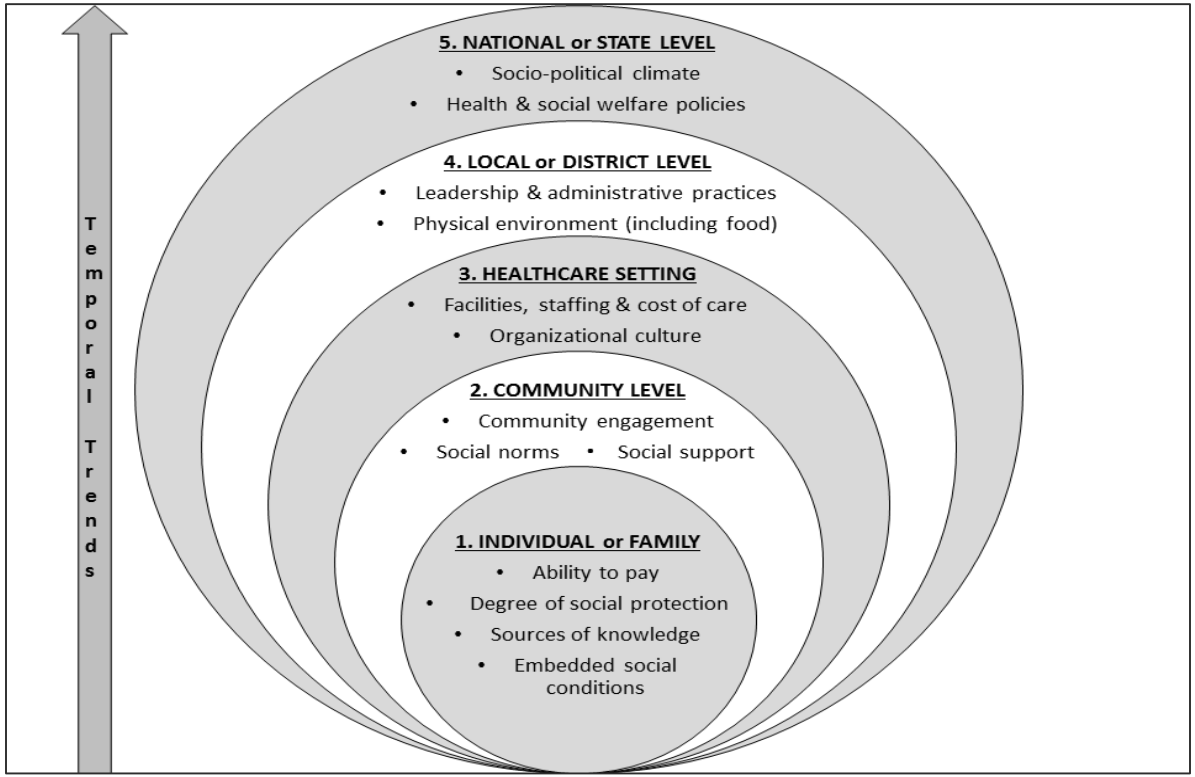
Context—Multiple Levels



Daivadanam et al. Forthcoming

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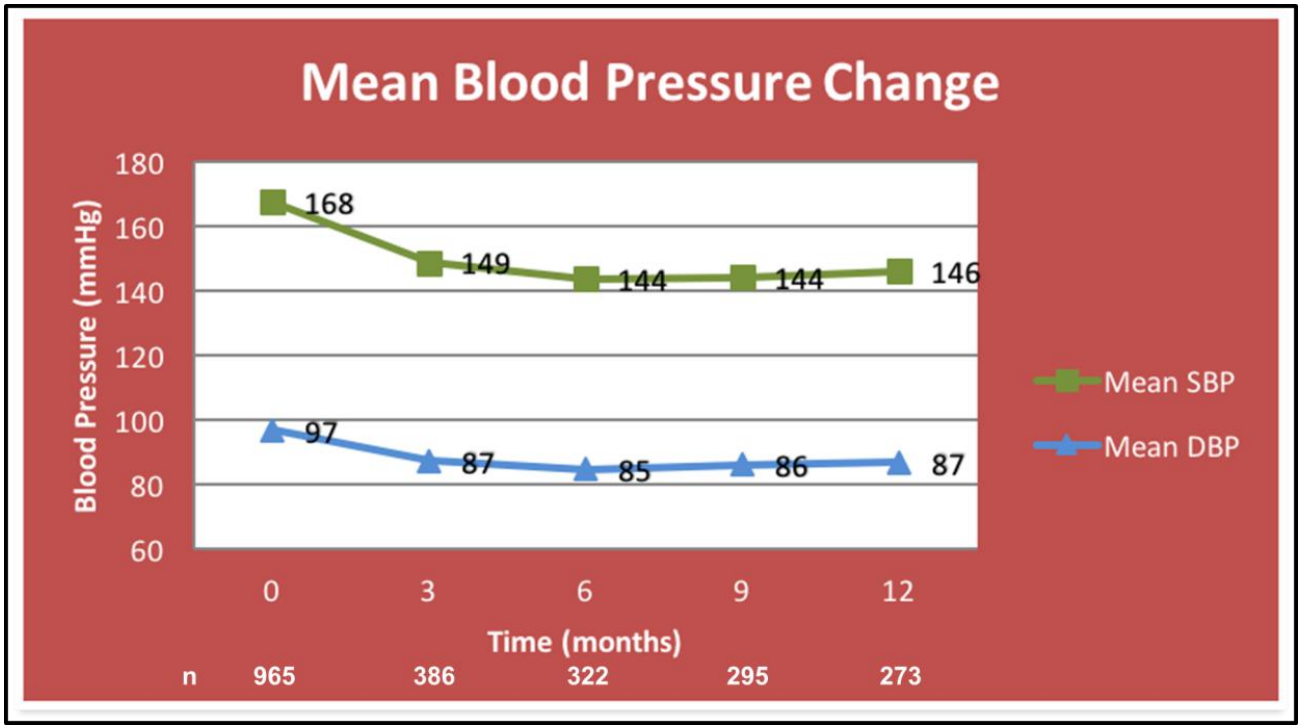
Nurse Mgmt of HTN: Impact



Kumar et al (2016) ACC Scientific Sessions

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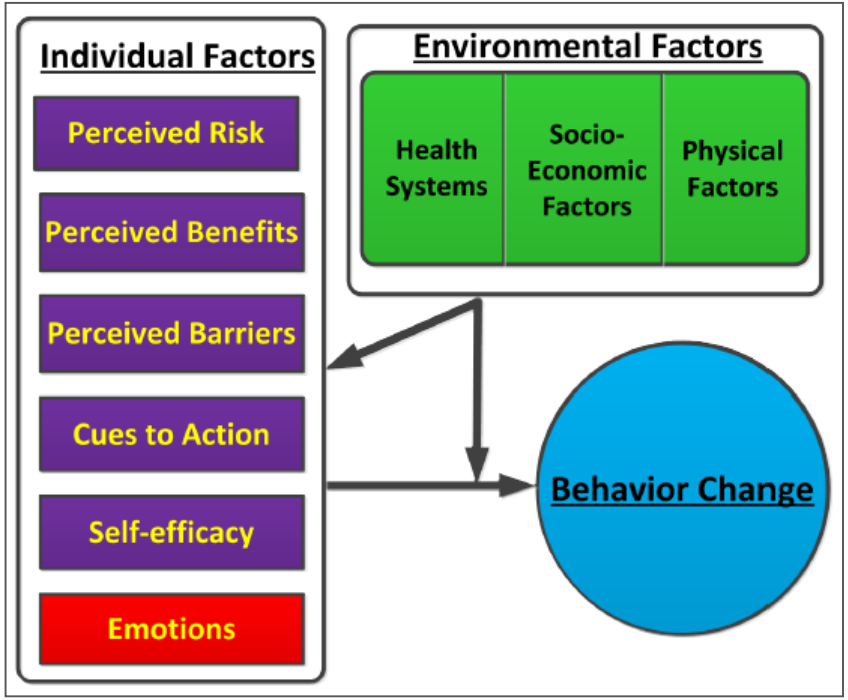
Optimizing **L**inkage **a**nd **R**etention to Hypertension Care in **K**enya: LARK Hypertension Study

PI (USA): Valentin Fuster, MD PhD

PI (Kenya): Jemima H. Kamano, MMed

NYU Langone Health

Using Context to Inform the Intervention



Naanyu, Vedanthan, et al, (2016) JGIM

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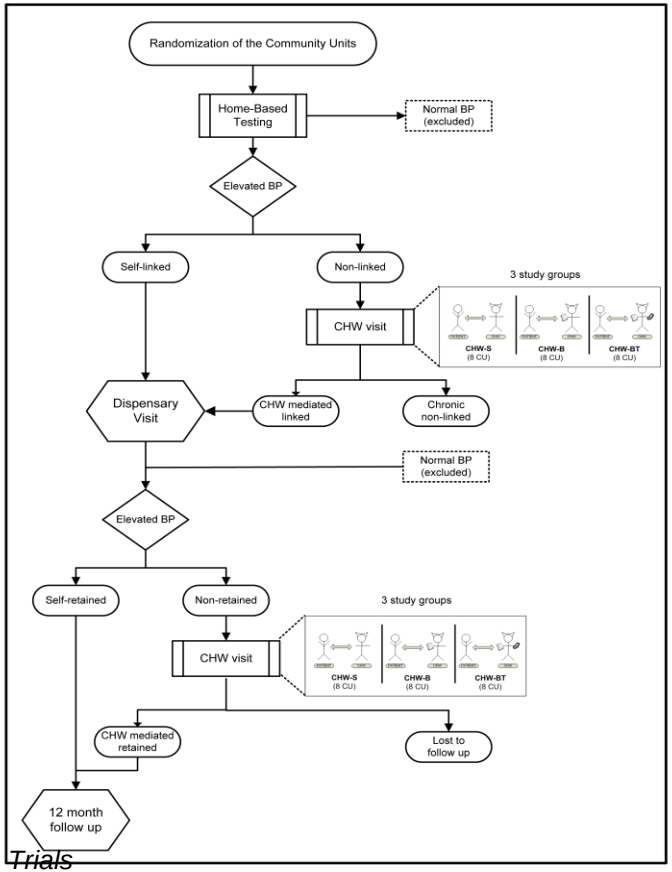
LARK: Cluster RCT



1. Usual care
2. Communication Strategy/ Motivational Interviewing
3. Smartphone-based tool

- 24 clusters: 8 clusters/arm
- F/U 1 year
- Co-primary outcome
  - Linkage to care
  - Change in SBP

Vedanthan et al. (2014) *Trials*

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Economic Reality

Variable	Statistic	Female (n=740)	Male (n=538)	OR	P-value
Age‡	Median (Range)	54 (18,116)	56 (18, 95)	1.00	0.43
Unemployment	% (n)	29 (211)	13 (71)	2.62	<0.001
Monthly Earnings < 5000 Ksh/mos*‡	% (n)	72 (380)	54 (250)	2.41	<0.001
Health Insurance Coverage	% (n)	13 (98)	17 (93)	0.74	0.05

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Vedanthan, et al (2016) AHA Scientific

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Food and Income Security

Poultry

Health Insurance

School fees

Farming

Commitment accounts

Business

Farm Inputs

Employment

Social welfare

GISHE

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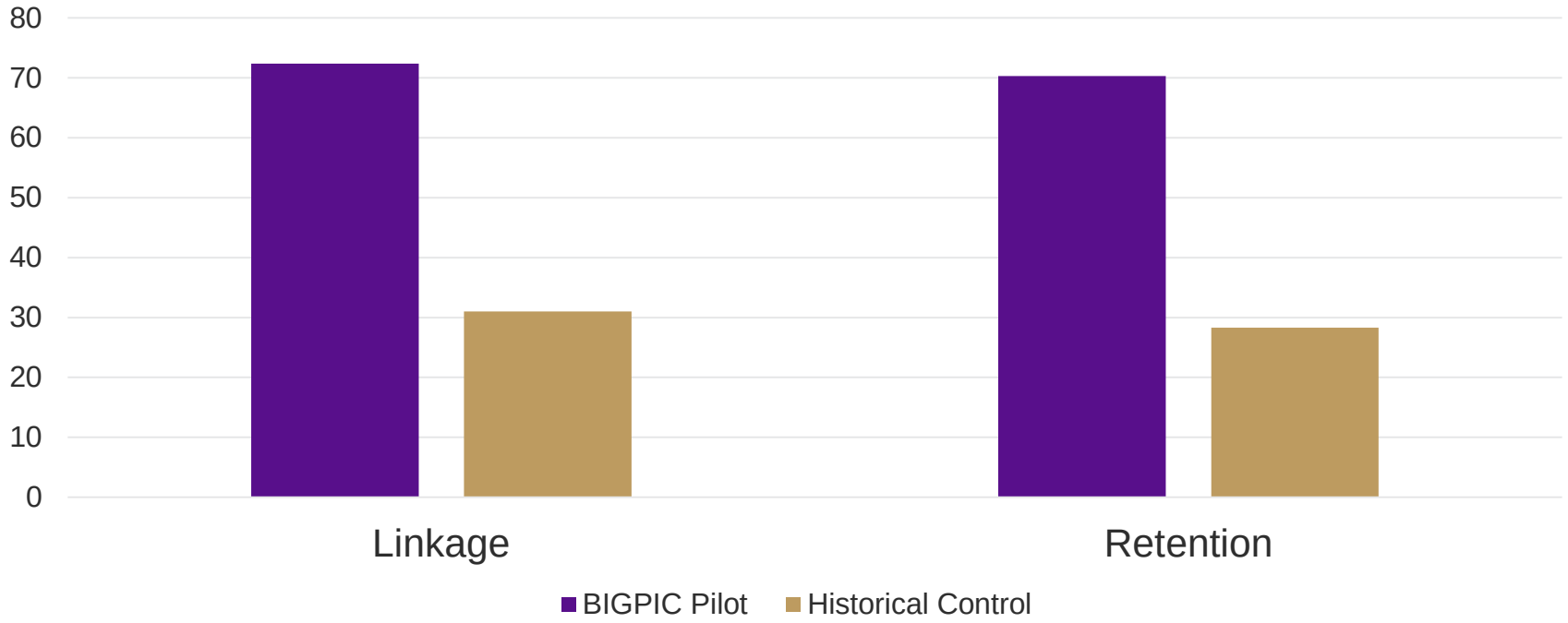
BIGPIC Pilot—Linkage and Retention



Pastakia et al. (2016) JGIM

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Bridging **I**ncome **G**eneration with Grou**p** **I**ntegrated **C**are

PI (USA): Rajesh Vedanthan, MD MPH

PI (Kenya): Jemima H. Kamano, MMed

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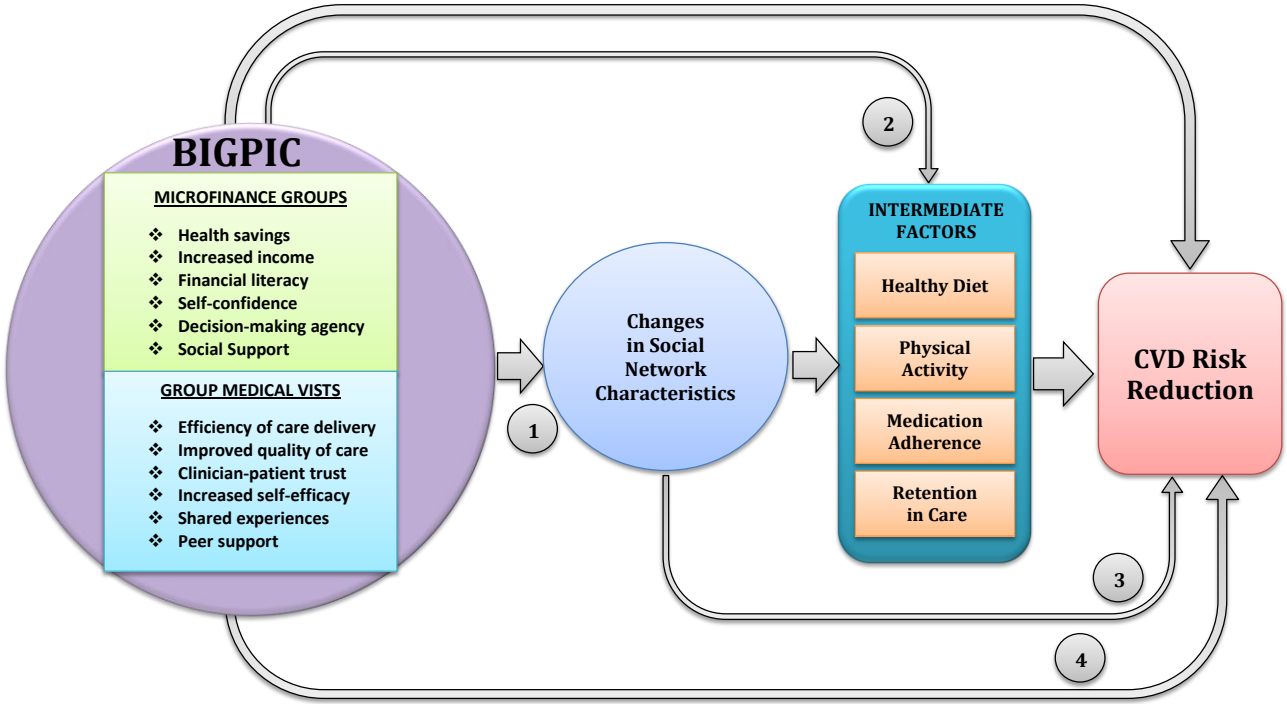
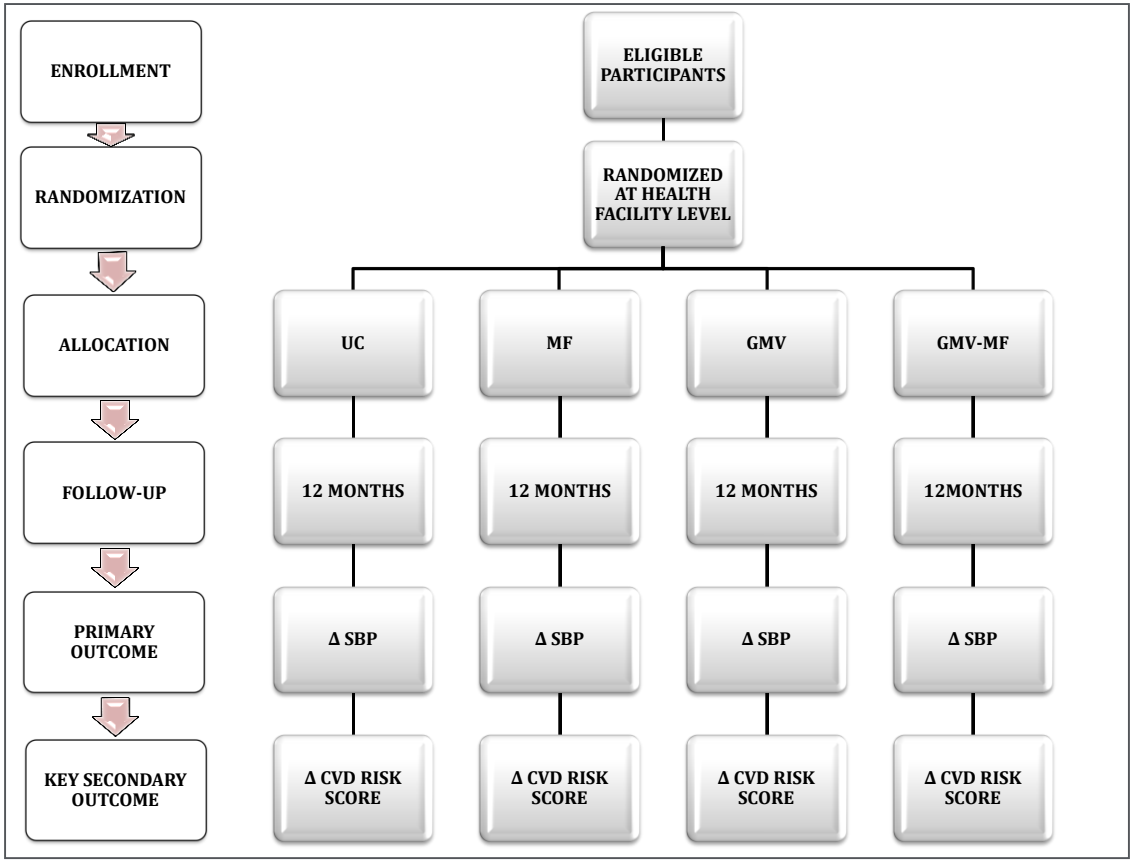
Innovative Care Delivery



Vedanthan, et al, (2017) Am

BIGPIC: Cluster RCT



Vedanthan, et al, (2017) Am

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Economic Reality: LARK

Variable	Statistic	Female (n=740)	Male (n=538)	OR	P-value
Age‡	Median (Range)	54 (18,116)	56 (18, 95)	1.00	0.43
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Health Insurance Coverage	% (n)	13 (98)	17 (93)	0.74	0.05

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Economic Reality: BIGPIC

Income Category	Women	Men
Less than Kshs 1000	36%	17%
Kshs 1000-2999	23%	18%
Kshs 3000-4999	13%	24%

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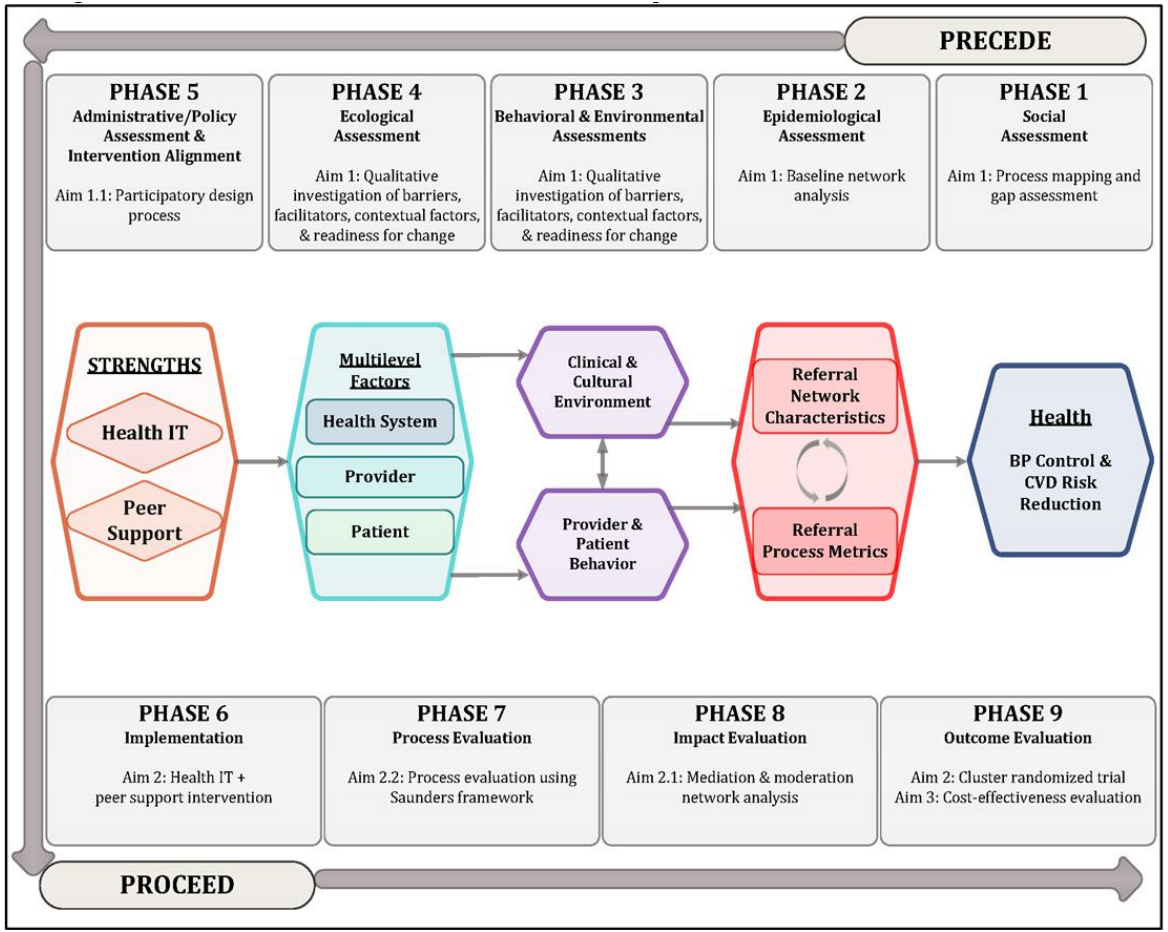
STRENGTHS



Mercer et al. Forthcoming

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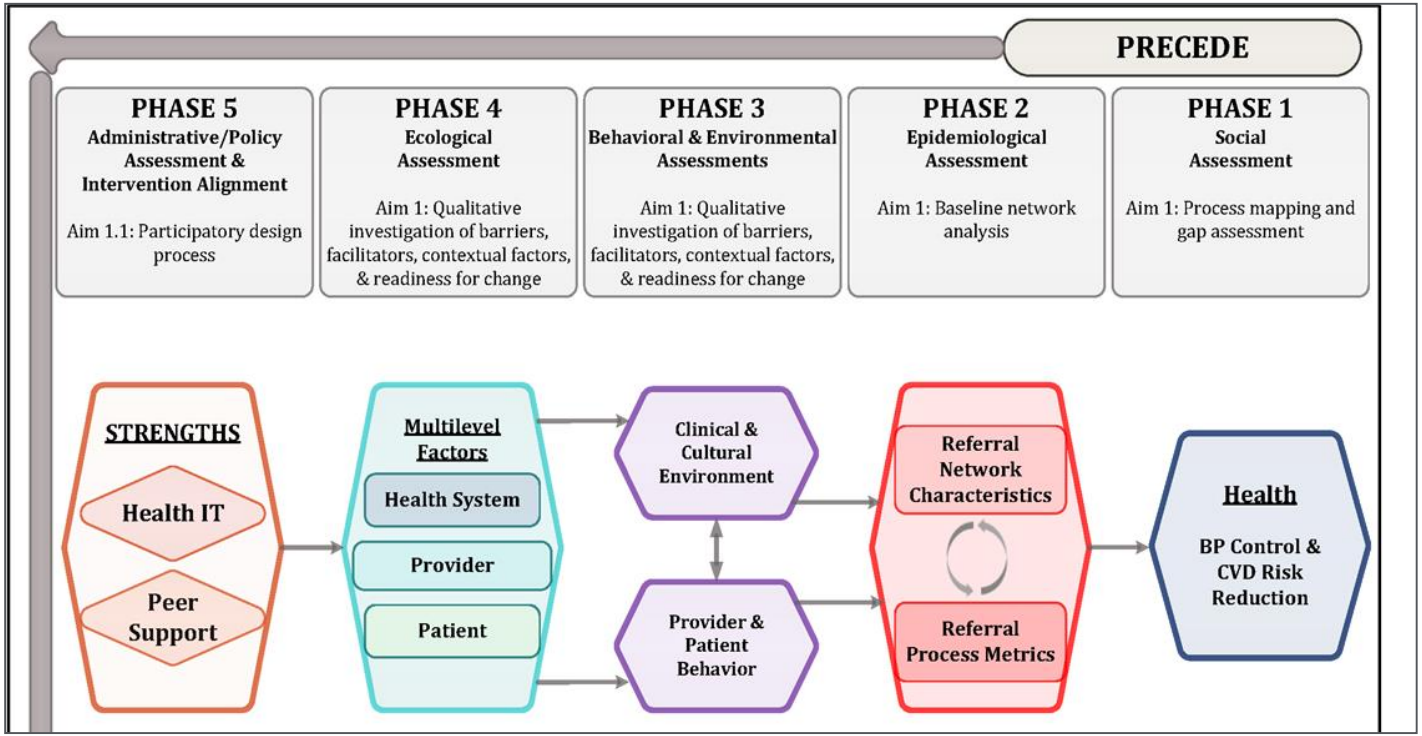
STRENGTHS: PRECEDE



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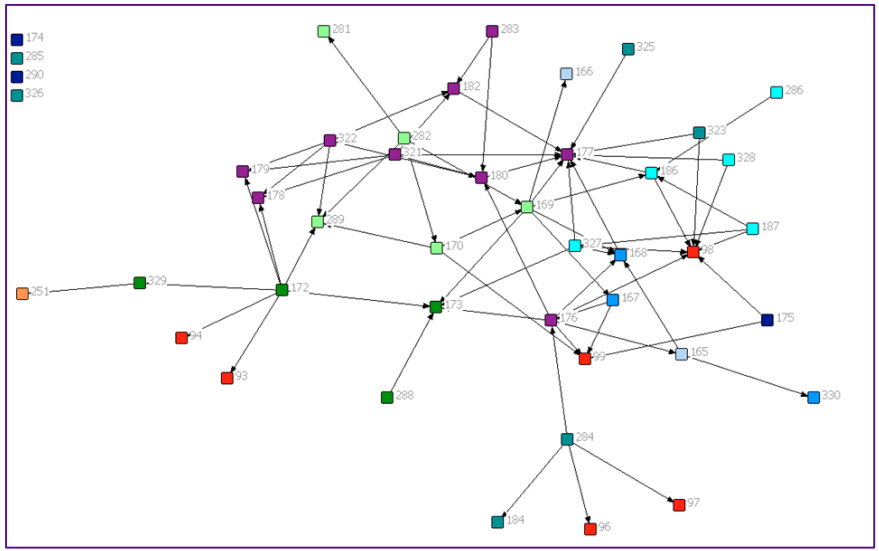
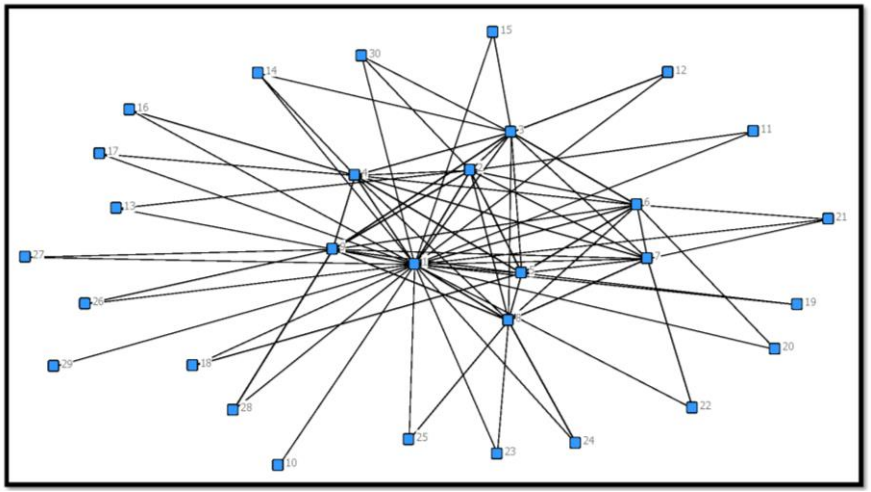
STRENGTHS: Referral Network Analysis





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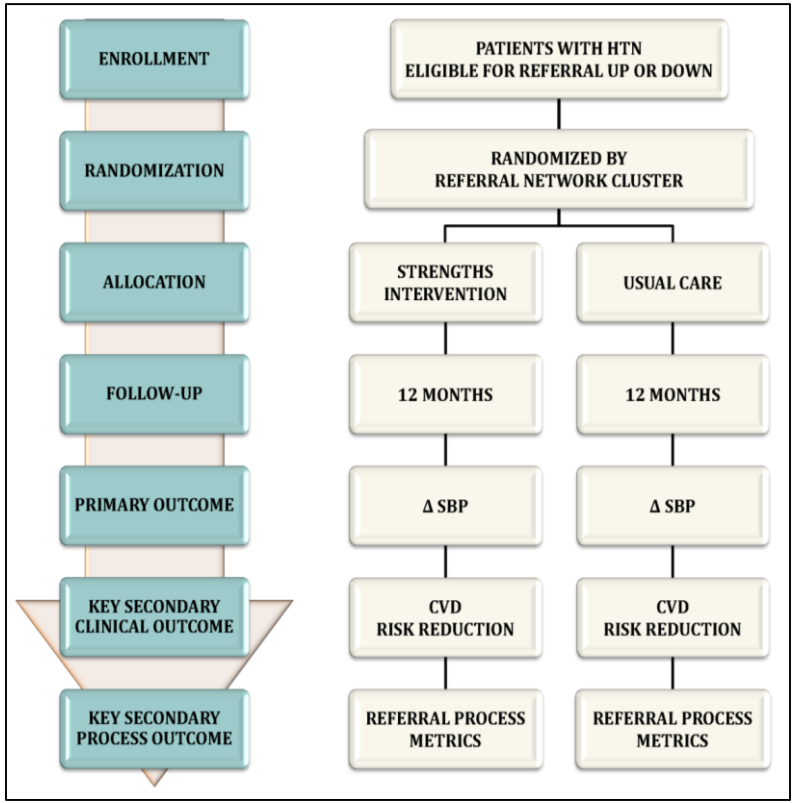
STRENGTHS



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THANK YOU

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