

Closing the treatment gap: research approaches to implementing what we know works in routine health care in developing countries

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Outline

- Task-shifting to overcome a major barrier to implementing what works
- Lessons from the MANAS trial, India: the importance of formative and pilot research for intervention development

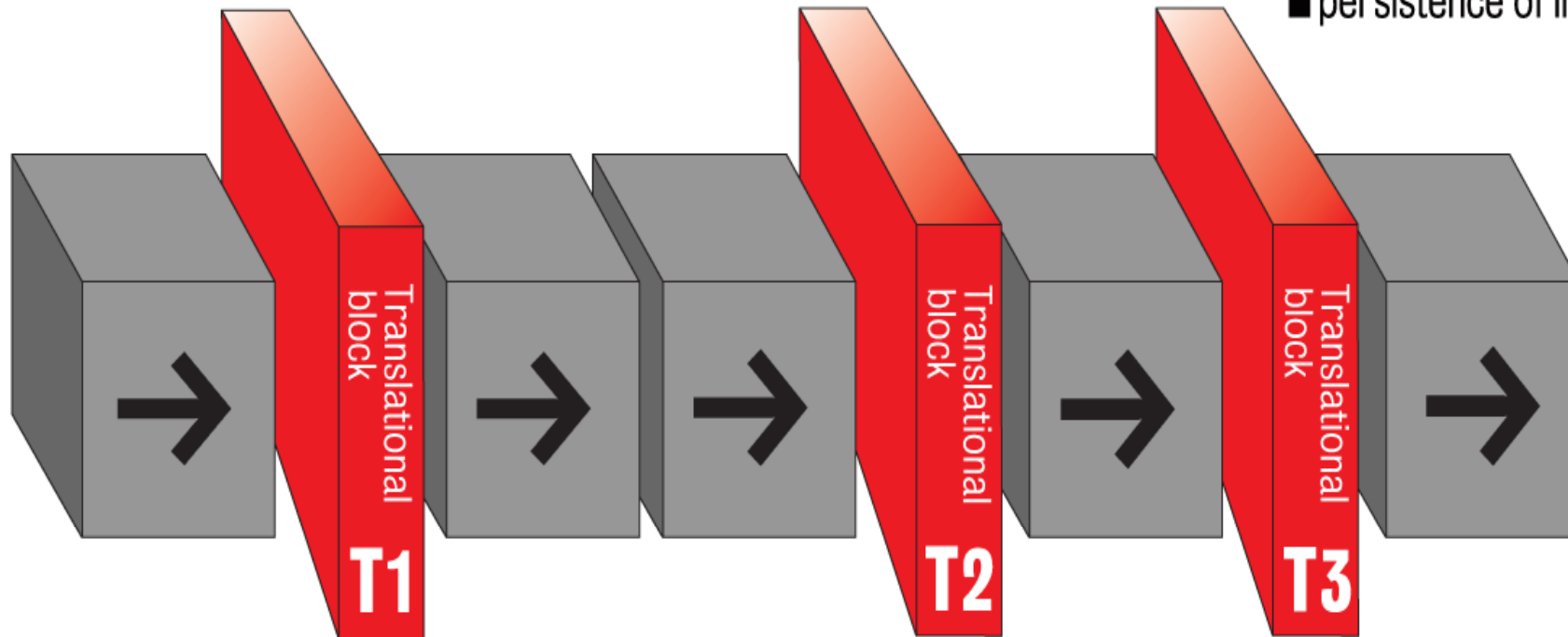
Phase 0
Basic
science
discovery

Phase 1
Early
human
trials

Phase 2
Early
clinical
trials

Phase 3
Late
clinical
trials

Phase 4
Implementation
■ adoption in principle
■ early implementation
■ persistence of implementation



Scaling up

- Integral part of the lexicon of global health
- “increasing the coverage of services based on the evidence derived from experimental research, leading to improve health outcomes in the target population”
- Research needed to overcome T2 and T3

Barriers to scaling up what we know works

- Several barriers at different levels of the health system
- Key barrier: human resources
 - Assumption is that all health care interventions needs professionally qualified practitioners

Task-shifting to close HR gaps

- the strategy of rational redistribution of tasks among health workforce teams,
- specific tasks are moved, where appropriate, from highly qualified health workers to health workers with shorter training and fewer qualifications in order to make more efficient use of the available human resources for health.
- Task-shifting is a “complex” intervention



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

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

April 2000

“Complex interventions in health care comprise a number of separate elements which seem essential to the proper functioning of the intervention although the “active ingredient” of the intervention that is effective is difficult to specify”

Task-shifting are complex interventions

- Because they involve multiple components and behavioural factors
- Need for systematic formative and pilot research in an iterative process to develop an acceptable, feasible and scalable intervention before evaluation of effectiveness

Lessons from the MANAS trial



Mental health resources and needs

- Mental health resources in the USA

- 300 million people
- 50,000 psychiatrists

- Mental health resources in India

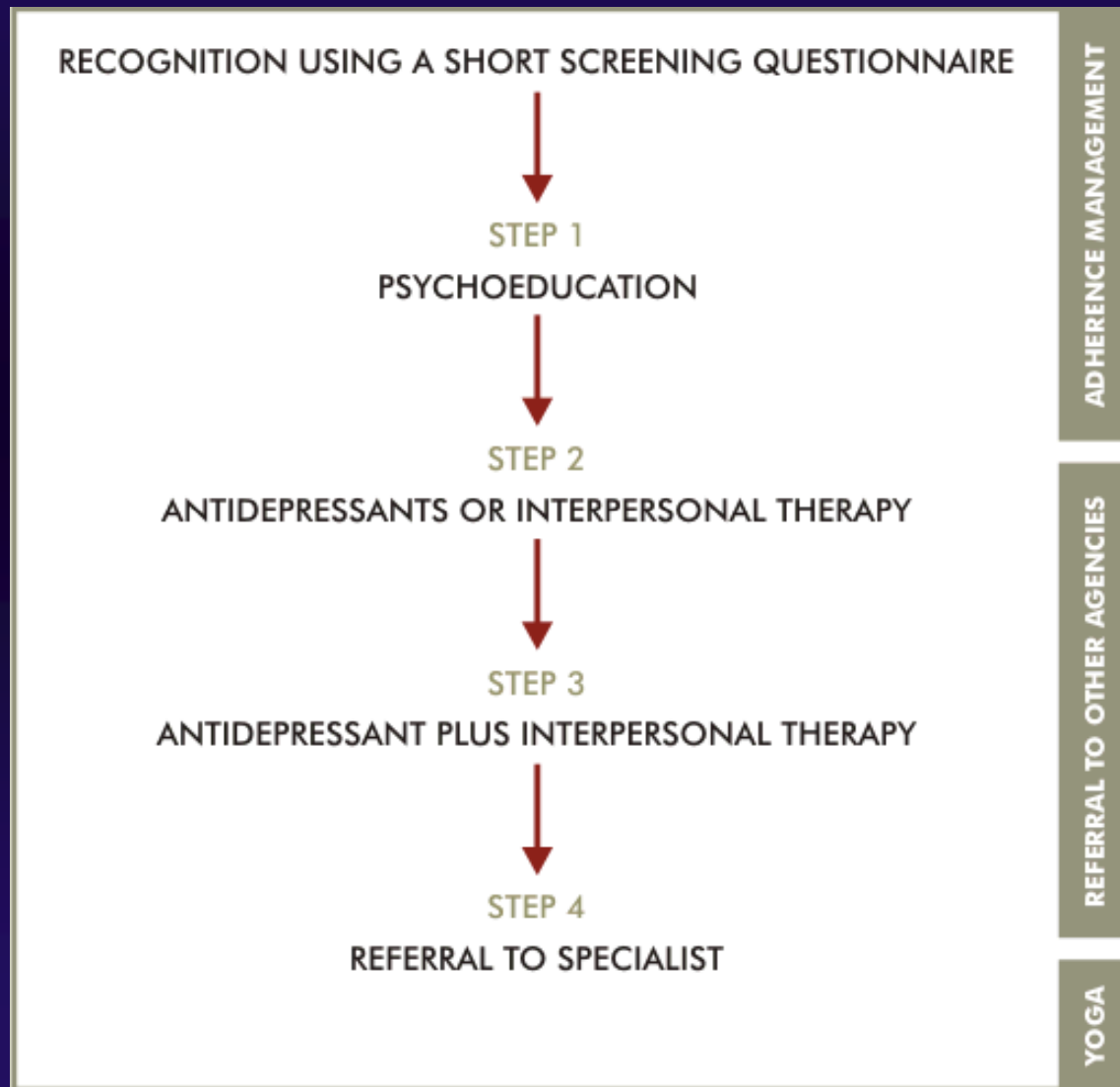
- 1.1 billion people
- 3000 psychiatrists

- WHO Mental Health Atlas 2005

The MANAS trial

- Evaluated the effectiveness of a lay health worker led Collaborative Stepped Care intervention for the treatment of Common Mental Disorders in Primary Health Care in of Goa, India in a cluster RCT
- Largest trial in psychiatry in the developing world with over 2700 participants recruited from 24 primary care clusters from the public and private sectors

Collaborative Stepped Care Intervention



The goals of formative research

- Defining/ modifying evidence based components of the intervention at early stages of development
- Evaluating acceptability and feasibility in specific contexts

Key questions during this phase

- What is the relevance of the intervention components: are they important, are they appropriate?
- What is the acceptability and feasibility of various modes of delivery, for e.g.
 - Lay person delivery
 - intensity of intervention
 - content of intervention
 - Location of delivery
 - Intensity and type of supervision
- What are the barriers to delivery, for e.g. time, money, resource constraints

Who was involved?

- Experts
- Patients
- Families
- Service providers

What did it involve?

- In-depth interviews
- Discrete choice experiments
- Testing components of the intervention in different contexts and delivery formats

Piloting

- “A process by which members of the target population are exposed to intervention” to:
 - Test the intervention as it is planned to be delivered
 - Gather information vital for the main evaluation

The goals of piloting

- To understand process of implementing intervention
- To identify barriers to feasibility & acceptability, e.g. time, money, other constraints
- Test methods of overcoming these

Some questions during this phase

- Fidelity of delivery - extent to which an intervention is implemented as intended
- Usefulness of the materials and components
- Training and supervision and quality assurance methods
- Effects of the intervention on outcomes/ processes
- Contextual influences and variations (for e.g. social and cultural background)

What were the effectiveness considerations at this stage?

- Testing effect of individual and combinations of components
- Testing in different settings
- Testing “doses”, order or forms
- Testing intensity, duration

Why do formative, piloting work?

- To optimise the likelihood of a feasible, acceptable intervention for evaluation
- To address barriers and enhance likelihood of effectiveness and scalability

In a nutshell

- To “distinguish between interventions that are inherently faulty (failure of intervention concept or theory) and those that are badly delivered (implementation failure)”.

RESEARCH REPORT

Integrating evidence-based treatments for common mental disorders in routine primary care: feasibility and acceptability of the MANAS intervention in Goa, India

SUDIPTO CHATTERJEE^{1,2}, NEERJA CHOWDHARY¹, SULOCHANA PEDNEKAR¹, ALEX COHEN³, GRACY ANDREW¹, RICARDO ARAYA⁴, GREGORY SIMON⁵, MICHAEL KING⁶, SHIRLEY TELLES⁸, HELEN WEISS², HELENA VERDELI⁷, KATHLEEN CLOUGHERTY⁷, BETTY KIRKWOOD², VIKRAM PATEL^{1,2}

Chatterjee et al, World Psychiatry 2008

Effectiveness of an intervention led by lay health counsellors for depressive and anxiety disorders in primary care in Goa, India (MANAS): a cluster randomised controlled trial



Vikram Patel, Helen A Weiss, Neeraj Chowdhary, Smita Naik, Sulochana Pednekar, Sudipto Chatterjee, Mary J De Silva, Bhargav Bhat, Ricardo Araya, Michael King, Gregory Simon, Helen Verdelli, Betty R Kirkwood

Summary

Background Depression and anxiety disorders are common mental disorders worldwide. The MANAS trial aimed to test the effectiveness of an intervention led by lay health counsellors in primary care settings to improve outcomes of people with these disorders.

Methods In this cluster randomised trial, primary care facilities in Goa, India, were assigned (1:1) by computer-generated randomised sequence to intervention or control (enhanced usual care) groups. All adults who screened positive for common mental disorders were eligible. The collaborative stepped-care intervention offered case management and psychosocial interventions provided by a trained lay health counsellor implemented by

Lancet 2010; 376:

Medical Research Council
Tropical Epidemiology Group
(H A Weiss PhD), Faculty of
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Health, London School of
Hygiene and Tropical Medicine
(Prof V Patel FMedSci,
M J De Silva PhD,

Patel et al, Lancet 2010

Conclusions

- Formative and piloting work are a key steps in development of a task-shifting interventions (indeed any public health intervention) before it is subjected to formal evaluation of effectiveness



Development and Evaluation of Complex Health Care Interventions

Short course

7 th - 12 th November, 2011

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