A graphical method for depicting randomised trials of complex interventions

Making the what, when, and who of non-drug treatments easier to understand would benefit researchers and readers, say **Rafael Perera and colleagues**

Complex interventions consist of several separate components combined to produce a desired outcome.[1] Evaluation of such interventions in randomised trials will generally lead to complex comparisons between trial groups.[2] Moreover, text descriptions in journal articles may obscure aspects of the interventions in the trial and hinder comparison between them. To counter these problems we have produced a single image that presents the components of all interventions in the trial and compares different treatment arms. The aim is to clarify the structure of the contrasted interventions and thus aid interpretation of the trial results.

The need for clear comparisons

We studied 169 randomised trials of non-drug interventions in primary care published between 1999 and 2003. We searched Medline, PSIQInfo, Bioabstracts, and Embase using the free text search terms "randomised controlled trials" and "primary care" and their synonyms, and excluding the term "placebo" appearing in the title or abstract; we also hand searched reference lists of retrieved papers. In many of these papers the interventions were incompletely described. We identified three principal problems: identifying the different components of the intervention, establishing the time at which components were delivered, and defining the differences between intervention arms.

To clarify these aspects we suggest that it would be helpful to depict the experimental and control interventions graphically. The proposed graph is similar to a flowchart, with each treatment arm represented in a specific column, and with all the intervention components presented within that column. The time scale of the trial runs from top to bottom on the left hand side, with the times of randomisation and outcome measurement (or measurements) clearly marked. Each component of an intervention is depicted separately. Components delivered concurrently are displayed side by side, while those delivered consecutively are shown one beneath the other.

We regard components either as objects or activities. Objects are represented by squares (to reflect their fixed nature) and activities by circles (to reflect their flexibility). Different components are labelled with different letters. Below the diagram, a legend gives a brief description of each component, including its form, content, functions, and details of who delivers it. If necessary, additional material can be given in the text. This approach will convey as much information as a written description, will clarify the basic structure of the experimental intervention, and elucidate the differences between treatment arms, as the examples below show.

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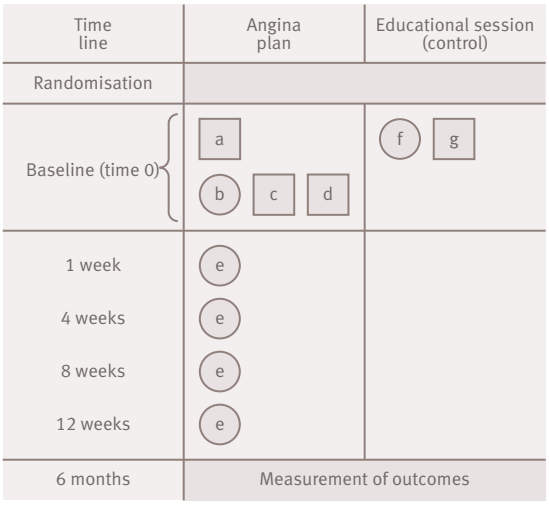
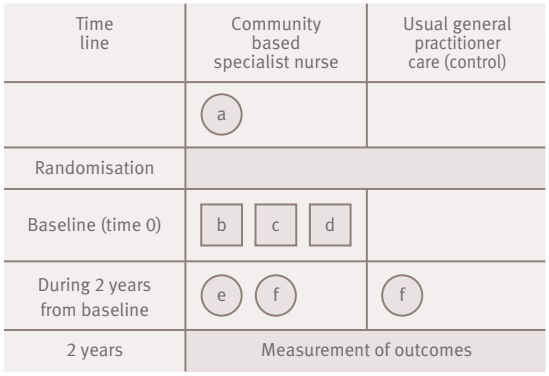


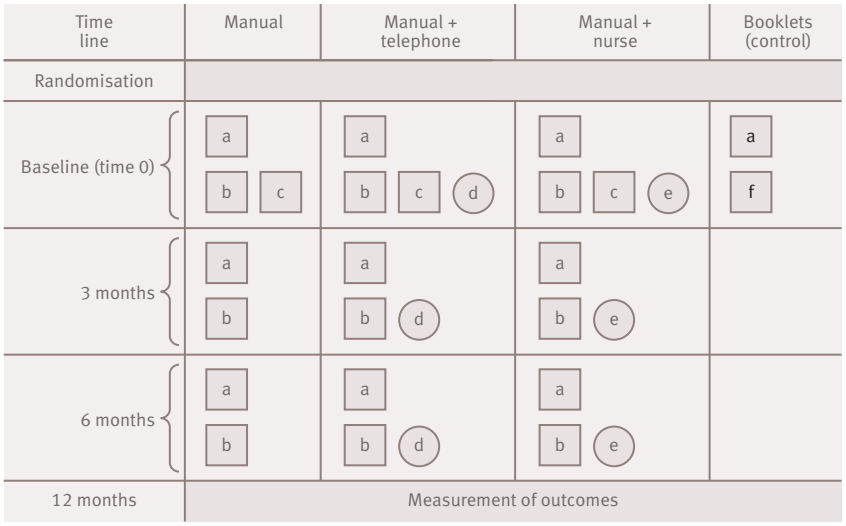
a	Questionnaire completed by patient to elicit whether he or she has any of the common misconceptions about angina
b	30-40 minute structured interview between patient (and partner if possible) and nurse. Nurse has extensive experience of running primary care secondary prevention clinics. Misconceptions discussed and corrected. Patient's risk factors for coronary heart disease elicited and methods suggested to reduce them by introducing lifestyle change
c	The angina plan, a 70 page work book handed to patient during interview. The plan uses cognitive behavioural techniques aimed at changing maladaptive coping practices and reversing disability (further details given)
d	Audiotaped relaxation programme handed to patient during interview. Patient asked to practice relaxation using the tape each day for 20 minutes
e	Phone call from nurse to patient (5-10 minutes). Success with goals rewarded with praise and encouragement; patient invited to extend goals
f	Patient educational session with the same nurse (length unspecified). Nurse identifies patient's risk factors from research clinic measurements and personal history. Nurse discusses with patient how risk factors could be reduced. Nurse responds to questions about each risk factor and about heart disease in general. Patient encouraged to discuss how it has affected his or her life
g	Package of written information about coronary heart disease (from British Heart Foundation and other authoritative sources) handed to patient during the educational session

Fig 1 | **Graphical depiction of interventions in a trial of self management in patients with newly diagnosed angina**



a	Course for nurses on meeting needs of people with Parkinson's disease and their carers (referenced)
b	Leased car given to specialist nurse
c	Mobile phone given to specialist nurse
d	Description of areas of responsibility given to specialist nurse. These are counselling and educating patients and carers about Parkinson's disease; providing information on drugs; monitoring clinical wellbeing and response to treatment, and reporting to doctors where appropriate; instigating respite or day hospital care where appropriate, seeing patients in hospital and liaising with hospital staff on patient discharge; assessing entitlement to state benefit; liaising with local primary care teams for ongoing care and treatment when
e	Nurse works under the guidance of a nurse manager, assuming the stated areas of responsibility. Clinical position of nurse is as adviser to general practitioner, rather than clinically autonomous
f	Usual care from general practitioner (details not given)

Fig 2 | Graphical depiction of interventions in a trial of community based nurses specialising in Parkinson's disease



a	Questionnaire to determine stage of change, processes of change, self efficacy and decisional balance of participant using the transtheoretical model
b	"Expert system" personalised (6-8 sided) letter sent, based on participant's responses to each questionnaire. This gave feedback on the stage of change, decisional balance, self efficacy, and the process of change, with second and third letters giving progress since the previous letter
c	*Pro-change programme for a healthier lifestyle*, a 64 page colour booklet enabling participants to stage themselves. Anglicised version of booklet used in American trials. Contains exercises to help participants move from their current stage. Sent on return of questionnaire
d	Telephone call made by trained lay person (three hours training) on return of each questionnaire; based on script and non-interactive
e	Appointment with nurse made on return of each questionnaire to discuss personalised letter, participant's progress with the pro-change programme, and to encourage its implementation
f	Four standard items of self help material: *Stopping made easier*, a 24 page manual; *The quit guide to stopping smoking*, a 12 page booklet; and 2 credit card sized reminder cards (Benefits of smoking cessation, Tips for staying quit) sent on return of questionnaire

Fig 3 | Graphical depiction of interventions in a trial of an expert system and self help manual to aid smoking cessation

Intervention intensity and repeated components

Lewin et al reported a parallel arm trial of self management in patients with newly diagnosed angina.[3] The experimental intervention introduces the "angina plan," the objective of which is to allow patients to manage their condition using cognitive behavioural techniques. The intervention is enhanced by nurse support in the form of interviews and telephone calls. The original paper describes the intervention in about 590 words.

With the aid of the diagram (fig 1) we can easily recognise that the experimental arm has a much more intensive intervention than the control, with repeated nurse telephone contacts at 1, 4, 8, and 12 weeks after the last contact in the control group. (An alternative way of depicting these repeated telephone contacts would be to use a single circle, and to label the time line with the four times of delivery.) The diagram also clearly shows that no component is common to both interventions.

Flexible interventions

Jarman et al reported a parallel arm trial of community based nurses specialising in Parkinson's disease.[4] The experimental intervention consists of training nurses to specialise in Parkinson's disease and, after clearly specifying their areas of responsibility, requesting them to support patients for the two year trial.

The diagram (fig 2) shows the resources needed for the community nurse intervention and also highlights the possible variation in the interventions in both experimental and control arms.In the experimental arm, the nurses are trained before randomisation; after randomisation (baseline) the nurses are given a car, a mobile phone, and a clear description of their areas of responsibility. Moreover, the timing of the intervention is not static; in both the experimental and control arms patient care is given at any point (and potentially at several times) in the two years that the trial lasts.

Multiple arms for multiple comparisons

Aveyard et al examined the effect on smoking cessation of the pro-change course.[5] The trial tested three experimental interventions using the pro-change course with increasing levels of contact (none, telephone call from lay person, and appointment with nurse). The control group received standard support

material. The written description of the interventions had 715 words. Our diagram (fig 3) shows immediately the cumulative nature of the experimental interventions.

Although each intervention is complex, the comparison between successive interventions is relatively simple, each differing from the last by a single component. The year long interval between the control intervention and trial outcome also stands out, in contrast to the six month interval in the experimental arms.

Advantages of using graphs

Graphical depiction of an entire intervention allows its structure to be quickly understood. With the experimental and control interventions placed side by side on the diagram, differences between them—such as in the time elapsing between their delivery and the trial outcome—become obvious.

We believe that the discipline of constructing a diagram will help at the design stage of a trial. By focusing attention on the components of the intervention, it prompts researchers to think through the structure, timing, and contents of each component in detail and to describe the components adequately.

The exercise should help to ensure that the control intervention has been adequately considered and described and that the difference between the experimental arm and the control arm is appropriate for measuring the effect of the intervention.

For the reader of the trial a graph will allow the details of an intervention to be quickly and easily grasped. Aspects that may be missed in a long verbal description stand out clearly, thus the differences between experimental and control interventions become obvious.

The CONSORT trial flowchart has improved transparency and accurate reporting of the numbers of participants at different stages of a study. We suggest that our proposed graphical method would similarly increase the clarity of reporting of complex intervention trials.

By focusing attention on the components of the intervention, it prompts researchers to think

SUMMARY POINTS

Complex interventions often require long explanations that are difficult to follow

Graphical representation could clarify descriptions

The graph would prompt researchers to focus on the structure and timing and ensure appropriate comparisons

Readers would be able to see the differences between comparison groups immediately

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The in-between world of knowledge brokering

For research findings to effectively influence health services' delivery of care needs an intermediary, says **Jonathan Lomas**

The ultimate aim of people engaged in health research is to get the health service's workforce, its employers, and its suppliers to have knowledge of facts (as represented by research results) and to use these facts in their practices, policies, and products. How well organised is research to achieve this aim? And how receptive and oriented are health services to this aim? The answers seem to be "not well organised" and "not very receptive." The interpersonal connections needed to bridge this know-do gap are not yet in place.[1] An emerging role therefore exists for knowledge brokers, supported by knowledge brokering resources and agencies, to fill the gap.

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Disconnection between research and health services worlds

The old adage "form follows function" is poorly reflected in the production and use of health research. The research world favours grant acquisition and academic publication over knowledge synthesis and engagement with the health service.[2] Researcher to researcher communication about the next study ("more research is needed") is well organised and all too common[3 4]; researcher to practitioner dialogue about implementing findings ("actionable messages") is poorly organised and all too rare.[5]

Structures and incentives in the health system do not