Developing and evaluating complex interventions: where to start?

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Symposium Overview

- Developing and evaluating complex interventions: the new Medical Research Council (MRC) Guidance
- A family centred approach to the management of lifestyle risk factors for recurrent stroke
- Addressing the tobacco and alcohol-related health promotion needs of people with learning disabilities
- Developing and testing smoking cessation support for people with severe and enduring mental health problems
Developing and evaluating complex interventions: the new MRC Guidance

Why new guidance?

- In 2000, the MRC published a Framework for the development and evaluation of randomised controlled trials (RCTs) for complex interventions to improve health.
- The Framework has been highly influential and the accompanying paper in the British Medical Journal (Campbell et al, 2000) has been widely cited.
- In 2006 it was decided that, while the initial Framework had been useful, it had a number of limitations, including:
  - The fact that it had adopted a model based on the 4 phases conventionally used in drug trials.
  - The linearity implied by the diagram of the model.
  - Limited guidance on how to approach developmental and implementation phase studies.
  - The assumption that conventional clinical trials always provide the best template for the evaluation of interventions.
The new Guidance

- What makes an intervention complex?
- The development-evaluation-implementation process (i.e. the new model)
- Developing a complex intervention
- Assessing feasibility and piloting methods
- Evaluating a complex intervention
- Implementation

MRC (2008)
What makes an intervention complex?

- Complex interventions are usually described as interventions that contain a number of components.

- There are several dimensions of complexity:
  - The interactions between the components of the intervention/s
  - The number and difficulty of behaviours required by those delivering or receiving the intervention
  - The number of groups or organisational levels targeted by the intervention
  - The number and variability of outcomes
  - The degree of flexibility or tailoring of the intervention
Implications for development and evaluation

- A good theoretical understanding is needed of how the intervention causes/might cause change
- Lack of impact may reflect implementation failure rather than genuine ineffectiveness
- It is likely that a number of primary and secondary outcomes measures will need to be developed/used
- Ensuring strict fidelity to a protocol may be inappropriate
Development-evaluation-implementation process (the new model)

Feasibility + piloting

Development

Evaluation

Implementation
Developing a complex intervention

- **Identifying the evidence-base**
  - Identify/conduct a systematic review

- **Identifying/developing theory/gathering evidence**
  - Develop a theoretical understanding of the likely process of change, by drawing on existing evidence and theory
  - Supplement, if necessary, by new primary research with key stakeholders

- **Modelling process and outcomes**
  - Basically designing the intervention and deciding what will be measured/assessed in terms of its effectiveness/delivery
  - Formal frameworks can be useful e.g. MOST (Collins et al 2005), RE-AIM (Glasgow et al 1999).
  - NICE (2007) has also produced guidance on the development and evaluation of behaviour change interventions
Assessing feasibility and piloting methods

- Methodological research suggests that this vital preparatory work is often over-looked or undertaken in a rather cursory manner.

- Evaluations are often undermined by problems of acceptability, compliance, delivery of the intervention, recruitment/retention and smaller than expected effect sizes.

- A mixture of qualitative and quantitative methods is likely to be needed e.g. to understand barriers to participation, to estimate response rates.
Evaluating a complex intervention

- Awareness of the whole range of experimental and non-experimental approaches should lead to appropriate methodological choices.

- Assessing effectiveness (e.g. randomised controlled trials, non-randomised designs, case control studies).

- Understanding the change process - a process evaluation, generally using qualitative methods, can provide insight into why an intervention fails/works.

- Assessing cost-effectiveness - an economic evaluation should be included, if possible, as this makes the results more useful for decision/policy-makers.
Dissemination + Implementation

- Dissemination - in order to increase the chances of getting findings translated into practice, they need to be made available using methods that are accessible and convincing to decision-makers.

- Passive strategies are known to be ineffective.

- Successful implementation of an intervention depends upon changing behaviour - often of a wide range of people.

- This requires an understanding of what needs to change, the factors maintaining current behaviour and barriers + facilitators to change.
Summary

- Developing a complex intervention
- Assessing feasibility + piloting methods
- Evaluation
- Implementation
References


A family-centred approach to the management of lifestyle risk factors for recurrent stroke

Dr Maggie Lawrence
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Dr Susan Kerr
Overview

• Background
• Aim
• Medical Research Council Framework
• Identifying/developing the evidence base
• Identifying the theory
• Modelling process & outcomes
Background

• Stroke incidence: 111,000 first ever strokes annually in the UK

• Recurrence: 25% within 5 years
  • increased level of disability, need for long-term care
  • death

• Risk factors
  • transient ischaemic attack (TIA), age
  • tobacco use, excessive alcohol consumption, unhealthy diet, physical inactivity
Aim

To develop a community-based, nurse-coordinated, family-centred behavioural intervention
Medical Research Council Framework

Development stage

1. Identifying/developing the evidence base
2. Identifying/developing theory
3. Modelling process and outcomes
Identifying/developing the evidence base

- Scotland-wide survey of stroke nurse practice
- Scotland-wide focus groups with people who have had a stroke & families
- Systematic review of effectiveness
- Wider reading of the relevant literature
- Consultation: stakeholders & project steering group
  - People who have had stroke & family members
  - Community lead nurse, Stroke Nurse Specialists, Stroke Nurse Consultant
  - Multi-disciplinary stroke clinicians: community & hospital based
  - Voluntary sector organisations
Survey of stroke nurse practice

- 97 completed questionnaires (55%)
- Assessment of lifestyle risk factors
  - Focus on tobacco use & alcohol
- Provision of information (written & verbal)
- One-to-one education
- Limited knowledge of guidelines & health-related recommendations
- Limited use of protocols/guidelines
- Limited use of validated assessment tools
Focus groups: to identify & explore factors that support or hinder lifestyle change

- Members of groups run by voluntary sector organisations
  - 29 people who have had a stroke, including 7 with aphasia & 20 family members

- Little or no information; lack of easy-access formats; family members felt excluded

- Effects of stroke may be barriers e.g. fatigue, impaired mobility, depression

- Confusing/contradictory health promotion messages

- Influence of family members
  - facilitate
  - hinder
Systematic review

To assess effectiveness of previously evaluated secondary prevention lifestyle interventions which addressed one or more lifestyle risk factors for recurrent stroke
Systematic review: results

• 3 papers
  • Shared care – hospital & GP
  • Nurse-led community-based
  • Nurse-led clinic-based
• Group work; one-to-one
• Medication compliance + at least one lifestyle behaviour
• Little significant effect in terms of behaviour change
  • Lack of theoretical underpinning (self-care model, 1 paper)
  • Short-term interventions
  • Lack of overt family involvement
Identifying/developing the theory

- Calgary Family Assessment/Intervention model (Wright & Leahey, 2005)
  - Structural
  - Developmental
  - Functional
- The Theory of Planned Behaviour (Ajzen, 1991)
  - Attitudes
  - Subjective norms
  - Perceived behavioural control
Calgary Family Assessment/Intervention model
(Wright & Leahey, 2005)
The Theory of Planned Behaviour

Behavioral Beliefs → Attitude Toward the Behavior → Intention → Behavior

Normative Beliefs → Subjective Norm → Intention

Control Beliefs → Perceived Behavioral Control → Intention

Actual Behavioral Control
MRC framework: Development stage

1. Identifying the evidence base
2. Identifying/developing theory
3. Modelling process and outcomes
Modelling process & outcomes

- Theory based
- Effects of stroke on individual (tailored)
- Family centred
- Long term intervention and follow-up
- Nurse education
  - Guidelines and assessment tools
- Accessible information
- Clear health promotion messages
Summary

1. **Identifying/developing the evidence base ✓**
   - Systematic review
   - Wider reading
   - Stroke nurse survey
   - Focus groups with patients and family members
   - Consultation with key stakeholders

2. **Identifying/developing theory ✓**

3. **Modelling process and outcomes . . .**
References


Tobacco and alcohol use in people who have a learning disability: giving voice to their health promotion needs

Mr Alan Middleton
Ms Lorna Fitzsimmons
Dr Maggie Lawrence
Dr Susan Kerr
Dr Chris Darbyshire
Overview

- Background
- Aim
- Medical Research Council Framework
- Identifying the evidence base
- Developing interventions
Background

• Health needs of people with Learning Disabilities (NHS Health Scotland, 2004)

• Lifestyles of people with Learning Disabilities

• Prevalence of smoking and drinking in people with Learning Disabilities

• Current evidence regarding Health Promotion interventions
Aim

To develop evidence-based tobacco and alcohol-related interventions
Medical Research Council Framework

Development stage

1. Identifying the evidence base
2. Identifying/developing theory
3. Exploring needs of people with learning disabilities
Identifying the evidence base

• 57 papers initially identified

• 5 papers met the study inclusion criteria

• The quality rating of the 5 papers was generally poor

• The review did provide some limited evidence on the feasibility and appropriateness of particular health promotion approaches.

• The review demonstrated that little is currently known about what approaches are effective in addressing the tobacco and alcohol-related health promotion needs of people with learning disabilities

• The review confirmed the need for research in this area
Identifying/developing theory

Social Cognitive Theory (SCT) (Bandura, 1986)
Exploring needs of people with learning disabilities

Aim:

To explore the tobacco and alcohol-related health promotion needs of people with mild/moderate learning disabilities

Focus on:

- factors that influence the use of tobacco and alcohol in this client group
- knowledge and understanding of the health risks associated with smoking and alcohol
- their health promotion needs
- appropriate health promotion approaches (including resources)
Exploring needs of people with learning disabilities

Qualitative study

- who took part?
  - Participants
    » people with LD (n=16)
    » carers (n=2)
    » professionals in community and primary care (n=15)

- how did we collect the data?
  - Focus groups (with people with learning disabilities)
  - Telephone interviews (with professionals and carers)

- how did we analyse the data?
  - Thematic analysis
Smoking & Physical Health

HP6 Psych: Yes, I think if it’s something particularly obvious to see, like a cough, they can relate to it and if it’s a bit more subtle, like the effects on their heart or circulation they might not see the link. I don’t think they would think: ‘If I’m smoking today I might get lung cancer in 20 years time.’ It’s very, very rare to come across somebody who could make that link and apply it to themselves.
Smoking & Impact of Health Promotion Messages

PwLD3 F: Aye that’s a good [advert] and then [you] see all the smoke going in like to the baby and everything, do you know what I mean, and all the smoke and everything, and then its going everywhere, do you know what I mean?
Smoking & Health Promotion Approaches

FC 14: I think a lot more visual things would be [better], maybe horrible and not very nice pictures ... it needs to be something visual
Alcohol & concept of Units

PwLD13 M: Why can you no' call it pints or glasses? I hate that word 'unit'! That's what drives people round the bend!
FC 14: A leaflet would be right over his head, I mean he is a clever laddie in his own way, but giving him a leaflet to read on you…shouldn’t drink because this and that, it would go over his head.
Nurse 15: I think basically whoever's involved with the person, there could be two or three different disciplines all involved with this person, and it's better that you deliver it in a coordinated style.
Appropriate health promotion approaches - access to health promotion

HP1 SW: A lot of the cessation groups you can get peer support, friendly up with somebody and support each other. I think, our client group might not get that, from a... mainstream smoking cessation clinic.
Appropriate health promotion approaches - the role of support

HP13 PN: It’s … just having people involved with them … like having the carer knowing exactly what is happening, ..if they have a carer, if they don’t have a formal carer, … having whoever, … that looks after them or is there for them can be involved as well.
Appropriate health promotion approaches - person centred focus

HP10 SW: I think it really does depend on individuals’... needs and abilities, ... what suits one person might not suit another ... having varied information ... video form, book pictures, ... for some people maybe something on tape, discs.
Modelling process & outcomes

• Developing Interventions
  • Flexibility and tailoring of intervention
    - multiple users
    - multiple outcomes
    - adaptable ‘person centred’
  • Developing in partnership
References


Developing and testing smoking cessation support for people with severe and enduring mental health problems

Dr Susan Kerr (PI), Prof. Robert Hunter, Dr Christina Knussen, Prof. Kate Davidson, Prof. John Norrie, Prof. Andrew Briggs, Prof. Hazel Watson, Prof. Robin McCreadie, Dr Murray Lough, Dr Barry Gibson-Smith, Ms Charlotte Woods
Funding Bodies (developmental study)
Overview

➢ Background

➢ Developmental stage

  • Identifying the evidence-base
  • Identifying/developing theory (including primary research)
  • Modelling process and outcomes

➢ Assessing feasibility and piloting methods
Background

- Physical health of this client group
- Prevalence of smoking
- Desire to stop smoking
- Limited evidence-base to guide practice/the delivery of services
Developmental Stage

Identifying the evidence base

- Systematic reviews of the literature x2; El-Guabaly et al (2002); Samele et al (2006)

- Interventions - generally combined behavioural interventions + pharmacotherapy (e.g. nicotine replacement therapy)

- Limited evidence to guide practice as the majority of the studies undertaken, to date, have lacked methodological rigour
Identifying/developing theory/gathering evidence

- Theoretical understandings of behaviour/behaviour change
  - Social cognitive theory (Bandura 1986)

- Primary research with key stakeholders
  - Setting: 3 NHS Boards in Scotland
  - Sample: people with moderate/severe mental health problems (n=27); health and social care professionals (n=60)
  - Data collection: audio-recorded individual interviews + focus group interviews

- Involvement of other stakeholders
  - Service users’ groups
  - Smoking cessation co-ordinators
  - ASH Scotland
  - NHS Health Scotland
  - Public health pharmacist
Findings - Research with key stakeholders

Barriers

- High level of physical + psychological dependence on nicotine
- Smoking used as an emotional coping resource
- Smoking used as a form of self-medicating
- Low levels of self-efficacy
- Fluctuating levels of motivation (often low)
- Concern about the negative impact on mental health if stop smoking
- Smoking habits of family + friends + professionals
- Previous failed smoking cessation attempts
- Lack of appropriate intensive behavioural support
- Knowledge, attitudes + skills of professionals
Research with key stakeholders (contd.)

Potential facilitators

- Concerns about health
- Concern about the price of tobacco (use of loose + illicit tobacco common)
- Successful cessation attempts in ‘significant’ others, including professionals
Modelling process and outcomes

- Development of the intervention/s
  - What should the various components be?
  - How will the intervention be delivered?
  - Where will the intervention be delivered?
  - Who will deliver the intervention?
  - How long will the intervention last?

- What methodological approach is most appropriate?

- How do we plan to recruit participants?

- Outcomes
  - What primary outcomes are we interested in?
  - What about secondary outcomes?
  - What processes will we explore?
Assessing feasibility + piloting methods

Study design

- mixed methods
  - randomised controlled trial (exploratory)
  - qualitative interviews

Setting + sample

- 3 NHS Boards (Scotland)
- 60 participants (ICD10 criteria)
- random allocation to 1 of 3 groups

Intervention groups (x2)

- Cognitive behavioural therapy + nicotine replacement therapy
- Cognitive behavioural therapy + motivational interviewing + nicotine replacement therapy

Control (x1)

- NHS Stop Smoking Service
Assessing feasibility + piloting methods (contd.)

Primary outcome measures
- expired carbon monoxide
- salivary cotinine (baseline)

Secondary outcome measures
- self-report smoking status
- psychiatric symptoms
- cognitive functioning
- health-related quality of life

Qualitative interviews
- Semi-structured telephone interviews (participants)
- Semi-structured face-to-face interviews (professionals who delivered the intervention)

Economic evaluation
- Costs + effects per quitter
- Cost per Quality Adjusted Life Year (QALY)
Summary

Developmental phase

- Identifying the evidence base ✓
- Identifying/developing theory ✓
  - Primary research with key stakeholders ✓
- Modelling process and outcomes ✓

Feasibility + piloting (proposal submitted)
References


Symposium Summary

- Overview of the new MRC Guidance
- Examples of 3 programmes of research lead by researchers at GCU that are utilising the framework
- Guidance provides a useful structure for both the development and evaluation of complex healthcare interventions
- Reference to the Guidance is useful in convincing funding bodies of the importance of developmental + feasibility/pilot work ahead of definitive trials/evaluations
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