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

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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 trails (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

MRC (2008)

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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)

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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

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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

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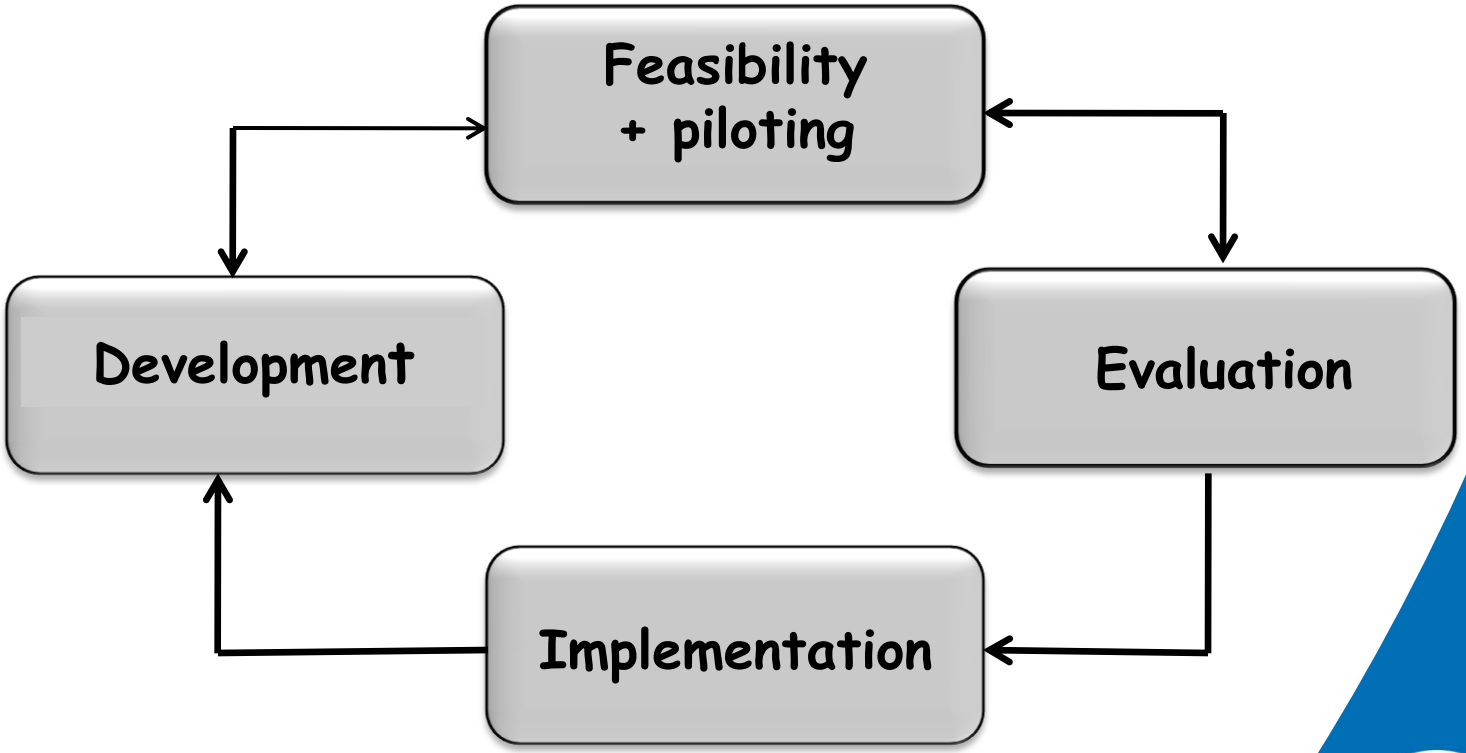
Development-evaluation-implementation process (the new model)



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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

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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

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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

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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

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Summary

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

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References

Campbell M, Fitzpatrick R, Haines A, Kinmonth AL et al (2000) Framework for the design and evaluation of complex interventions to improve health. British Medical Journal, 321: 694-6.

Collins LM, Murphy SA, Nair VN, Stretcher VJ (2005) A strategy for optimizing and evaluating behavioural interventions. *Annals of Behavioural Medicine*, 30(1):65-73

Glasgow RE, Vogt TM, Boles SM (1999) *American Journal of Public Health*, 89(1): 322-7

MRC (2008) *Developing and evaluating complex interventions: new guidance*, www.mrc.ac.uk/complexinterventionsguidance

National Institute for Health and Clinical Excellence (NICE) (2007) *Behavioural change at population, community and individual levels*, NICE Public Health Guidance. London: NICE

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

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Ms Caroline McVey,
Lisbeth Hockey Research Training Fellow
Dr Susan Kerr

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Overview

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

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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

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Aim

To develop a community-based, nurse-coordinated, family-centred behavioural intervention

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Medical Research Council Framework

Development stage

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

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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

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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

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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

Burdett Trust for Nursing

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Systematic review

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

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Evidence Based Care of Older People
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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

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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

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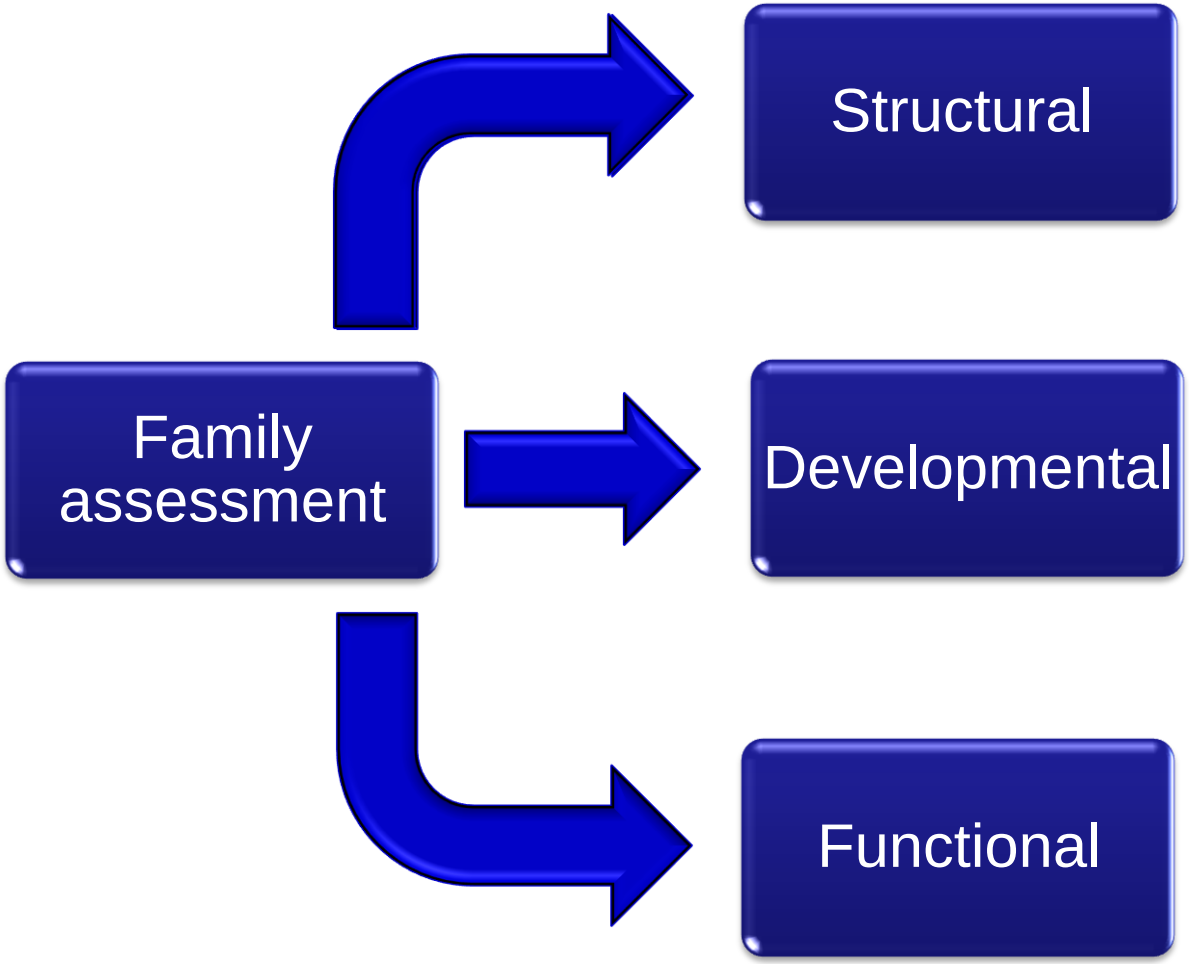
Calgary Family Assessment/Intervention model

(Wright & Leahey, 2005)



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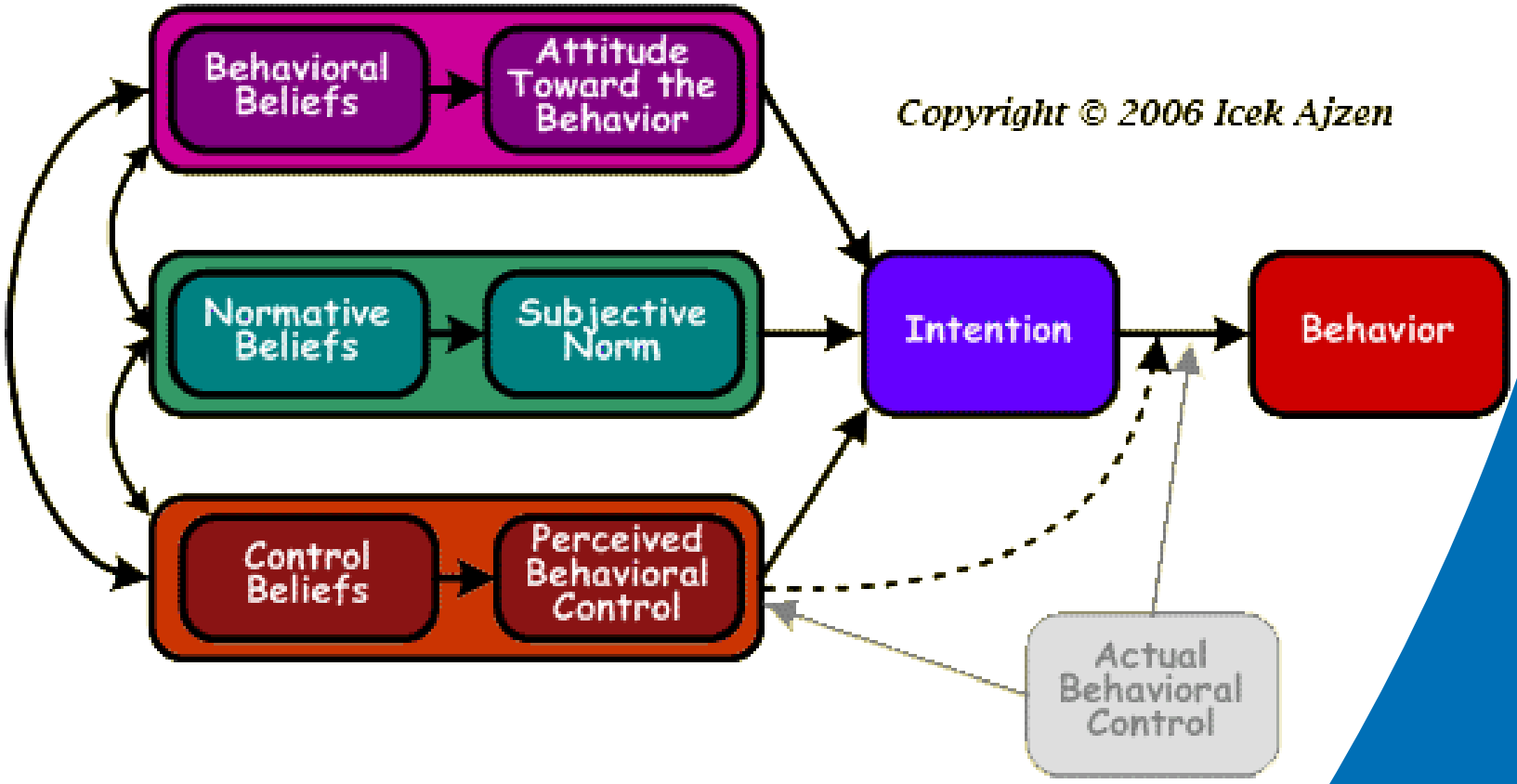
The Theory of Planned Behaviour



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MRC framework: Development stage

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

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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

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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 . . .**

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References

Ajzen, I. (1991) The theory of planned behaviour. Organizational Behaviour and Human Decision Processes; 50: 179-211.

Lawrence, M. et al (2010) What is the evidence for using family based interventions to prevent stroke recurrence? Nursing Times; 106: 22-25.

Lawrence, M. et al (2009) A systematic review of the effectiveness of secondary prevention lifestyle interventions designed to change lifestyle behaviour following stroke. [peer reviewed protocol] Available from: http://www.joannabriggs.edu.au/protocols/Protocol298.pdf

Lawrence, M. et al (2009) A summary of the guidance relating to four lifestyle risk factors for recurrent stroke: tobacco use, alcohol consumption, diet and physical activity. British Journal of Neuroscience Nursing (BJNN); 5: 471-476.

Lawrence, M. et al (2009) A survey of stroke nurses' knowledge and practice regarding four secondary prevention lifestyle issues: Tobacco use, alcohol consumption, diet and physical activity. BJNN; 5: 518-523.

Wright, L.M., Leahey, M. (2005) Nurses and families. 4th ed. Philadelphia: F.A. Davis Company.

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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

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Overview

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

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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

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Aim

To develop evidence-based tobacco and alcohol-related interventions

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Medical Research Council Framework

Development stage

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

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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

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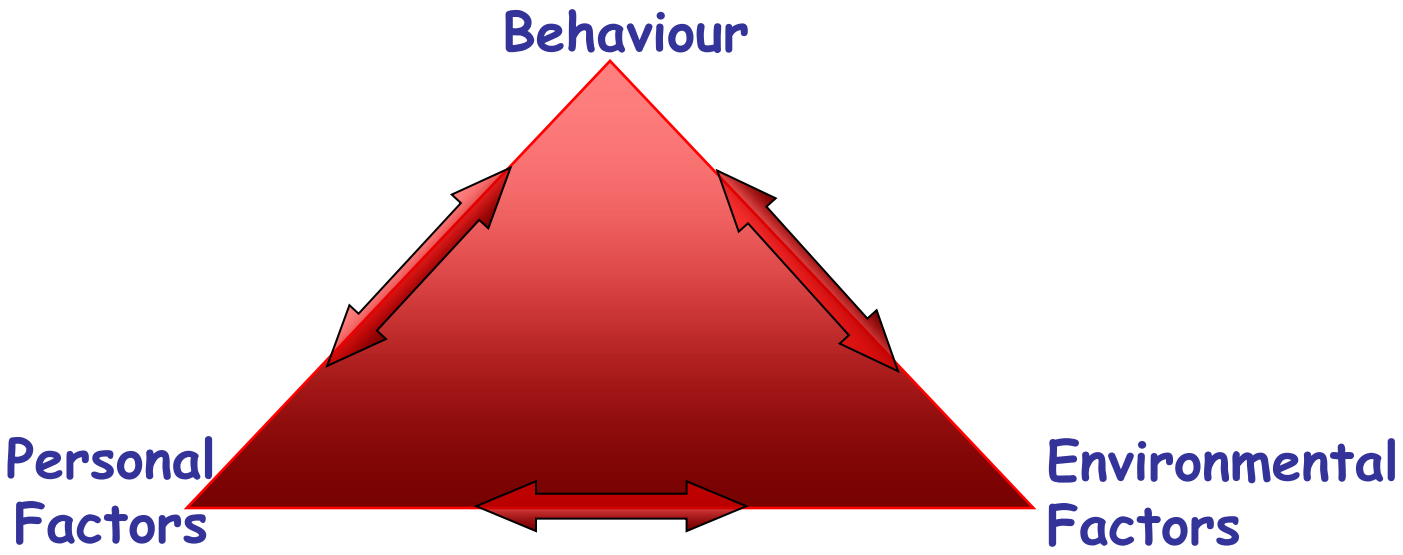
Identifying/developing theory

Social Cognitive Theory (SCT) (Bandura, 1986)



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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)

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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

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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.

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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?

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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

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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!

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Alcohol & Complexity of Health Promotion Materials

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.

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Alcohol & Interventions

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.

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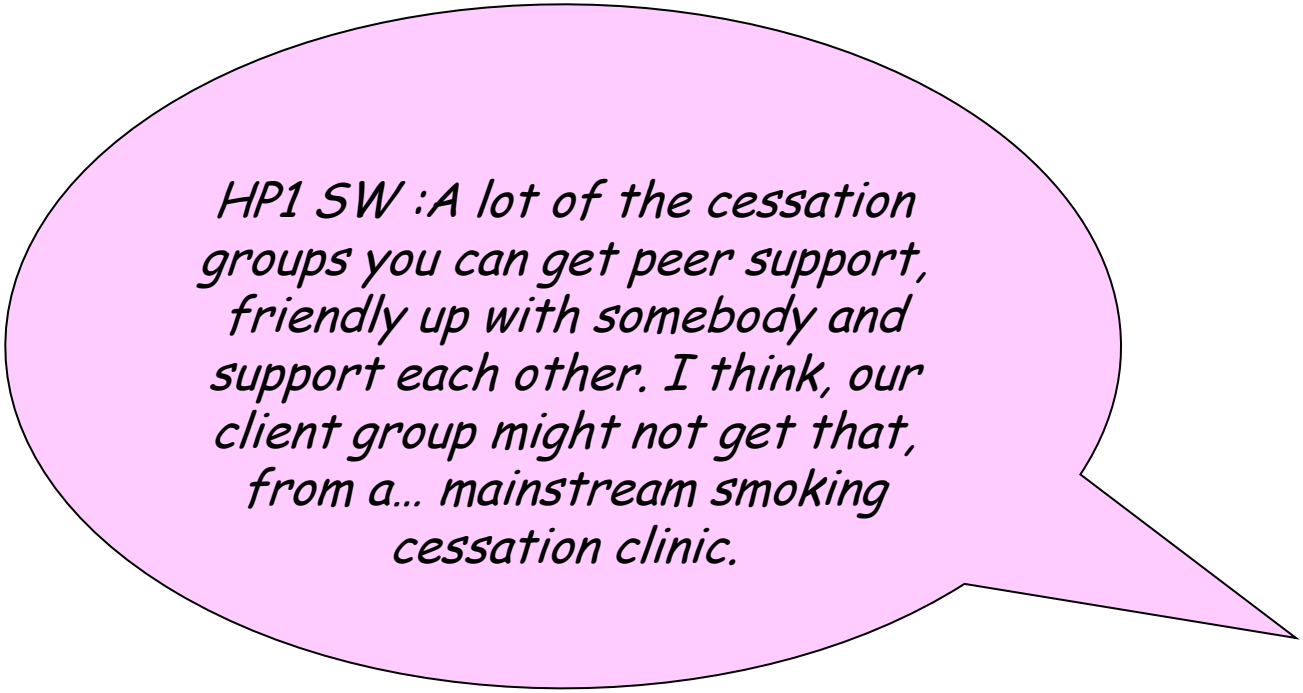
Appropriate health promotion approaches - access to health promotion



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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.

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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.

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Modelling process & outcomes

- **Developing Interventions**
  - Flexibility and tailoring of intervention
    - multiple users
    - multiple outcomes
    - adaptable 'person centred'
  - Developing in partnership

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References

- NHS Health Scotland, 2004. *Health Needs Assessment Report. People with Learning* Disabilities *in Scotland.* NHS Scotland: Glasgow.
- Bandura, A., 1986. *Social foundations of thought and action. A social cognitive theory*. Prentice Hall: Englewood Cliffs

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

Dr Susan Kerr (PI), Prof. Robert Hunter,
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Prof. John Norrie, Prof. Andrew Briggs,
Prof. Hazel Watson, Prof. Robin McCreadie,
Dr Murray Lough, Dr Barry Gibson-Smith,
Ms Charlotte Woods

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Funding Bodies (developmental study)

British Heart Foundation

CANCER RESEARCH UK

DH Department of Health

Diabetes UK

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

MRC Medical Research Council

r&d office

CHIEF SCIENTIST OFFICE

Llywodraeth Cynulliad Cymru
Welsh Assembly Government

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Overview

- Background

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

- Assessing feasibility and piloting methods

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Background

- Physical health of this client group
- Prevalence of smoking
- Desire to stop smoking

- Limited evidence-base to guide practice/the delivery of services

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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

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Developmental Stage (contd.)

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

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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-medication**
- 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**

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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

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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?

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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

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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)

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Summary

Developmental phase

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

Feasibility + piloting (proposal submitted)

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References

Bandura A (1986) Social foundations of thought and action: a social cognitive theory. Prentice Hall, NJ.

El-Guebaly N, Cathcart, J, Currie S, Brown D (2002) Smoking cessation support approaches for persons with mental illness or addictive disorders. Psychiatric Services, 53: 1166-71.

Samele C, Hoadley A, Seymour L (2006) A systematic review of the effectiveness of interventions to improve the physical health of people with severe mental health problems. Leeds: Sainsbury Centre for Mental Health.

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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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