Patient Education Interventions: Theoretical & Operational Considerations in Designing a Successful Trial

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Introductory Comments

• Which came first, the problem or the educational intervention?
• RCT v. program evaluation
• Funded trial with intent to disseminate

Overview

• Obtaining preliminary data
• Developing a theoretically grounded intervention
• Finding collaborators to complement your expertise (less emphasis here)
• Conducting pilot/feasibility studies
• Designing the RCT

Preliminary data

• What is the problem?
• How do you know it’s a problem?
  – What do you see clinically?
  – What does the literature say?

How will you convince others there’s a problem?

• Scope
  – Incidence & prevalence
  – Trajectory
• Impact
  – QOL
  – Cost
• Lack of attention in literature and from funders

Convincing others

• Use available literature whenever possible
• Conduct descriptive studies if you must -- these will always take longer than you think
• Try to separate “I don’t know” from “It isn’t known”
Descriptive studies

- Use standardized structured questionnaires with large samples
- And open-ended interviews with small samples
- In a new area one could spend years working toward an understanding of the problem
- Begin to prepare manuscripts while still collecting data

Developing the Intervention

Consider the type of problem (phenomenon) that you have
- Straight forward knowledge deficit
- Attitudes that are barriers to acting on knowledge
- Lack of motivation
- Skill deficit

Search Lit for Theories

- Transtheoretical Model/Stages of Change (Prochaska)
- PRECEDE-PROCEED
- Self Regulation (Leventhal)
- Self Determination (Deci)
- Self Efficacy (Bandura)

Theoretical Foundations of the Representational Approach to Patient Education

- Leventhal’s Common Sense Model
- Hewson & Thorley’s Theory of Conceptual Change

The Common Sense Model

- Individuals have illness representations (beliefs) about their health problems.
  - Identity
  - Cause
  - Timeline
  - Consequences
  - Cure/control
- Representations guide:
  - Reactions to information
  - Coping with health threats
Conceptual Change Model

Learning "is not simply the acquisition of a set of correct responses, a verbal repertoire or a set of behaviors," but rather it is a process of conceptual change.


Learning needs

- Gaps (missing information)
- Misconceptions
- Confusions

Conceptual change occurs

- When person is dissatisfied with current beliefs.
- When intelligent, plausible alternative information is offered.
- When new information is perceived to be beneficial.
- When the person has an opportunity to monitor & comment on their own ideas

Assumptions of the Representational Approach

- Patient’s have pre-existing representations regarding their illness.
- Any information we give will interact and be accepted or rejected based on those pre-existing representations.

Elements of the Representational Approach

- Representational Assessment
- Exploring gaps, misconceptions, & confusions
- Creating Conditions for Conceptual Change
- Introducing Replacement Information
- Summary & Reflection
- Goal setting & action planning (not in original)
- Follow up reinforcement (not in original)

RIDcancerPain

- Problem: Attitudinal barriers to pain management
- Population: Adults with cancer
- Recipients: Patients (or dyads of patient and significant other)
- Delivery system: In person counseling interview
Patient-Centered Advance Care Planning (PC-ACP)

- Problem: Inadequate decision-making about future medical care
- Population: ESRD
- Recipients: Patient and surrogate dyads
- Delivery system: In person counseling interview

Determine mode of delivery

- Face to face (individual, dyad or group)
- Telephone
- Internet
- Video/CD
- Mail written material

Consider the needed materials

- iPods
- Computers
- Information sheets or brochures
- Videotapes

Consider where you will likely deliver the intervention

- Clinic
- Patient’s home
- Work site
- Community center

Consider interventionist skill and training

- Discipline/profession
- Licensing/certification
- Proficiency test to pass?
- Match patients with interventionist on race/age/gender/other characteristics?

Develop an intervention manual

- Articles to read
  - Theory behind the intervention
  - The substantive problem
- Protocol – all steps to follow
- Clear directions on what to say & do and what not to say & do
- Manual forms the basis for tracking fidelity
Finding Collaborators: some examples

- Design and statistics – from day 1
- Methods experts (e.g. focus group leader)
- Clinical experts
- Clinical doorkeepers
- Technology experts (e.g. web design)
- Grant writers

Feasibility studies: Aims

Ability to recruit, retain, and collect complete data in a given period of time
Subject willingness to be randomized
Subject satisfaction with the intervention itself and with the methods used to test it, including acceptability of the questionnaires used to assess outcomes
- Use both structured satisfaction items and open-ended interviews
- Be careful to really engage the subject in helping you make the intervention better.

Feasibility studies: Aims continued

- Interventionist satisfaction with the intervention – talk about what “feels” right and what “feels” wrong in the protocol.
- Reliability (internal consistency) of the questionnaires in your sample
- Initial estimates of effect sizes – is there any evidence that your educational intervention is having the desired effect?

Designs

- Single-group pre-post
- Two-group RCT
- Other possibilities

Tracking fidelity: Enhancing Internal Validity

- Minimize drift in provider skills or actions
- Minimize between-provider differences
- Minimize contamination between conditions
- Use level of fidelity as a covariate

What a fidelity tool should measure

- Unique -- theoretically unique components (AKA active ingredients)
- Common -- non-specific factors/interpersonal skills
  » Establishing rapport
  » Using good eye contact
- Proscribed -- actions that are not desired
### Example of a Feasibility Study
(Heidrich, Ward, et al., 2003)

- 91% of CIS callers are willing to stay on the line to participate in a study after receiving service as usual.
- An adequate number of callers meeting specific eligibility criteria for the proposed study could be recruited -- 22 subjects who would be eligible for the trial called the CIS in a two-week period.

### Elements of an Efficacy Trial

- Theoretical underpinnings
- Logical hypotheses
- Pilot data
  - Subjects available
  - Effect sizes
  - Acceptability
- Subjects (inclusion & exclusion)
- Outcome measures
  - Valid
  - Reliable
  - Sensitive
- Intervention manual
- Fidelity plan
- Interventionist training
- The right control group
  - No treatment
  - Care as usual
  - By usual caregivers
  - By your study staff
- Wait list
- Statistical issues
  - Power
  - ITT or a good argument why not
  - Crystal clear link with hypotheses
- Timeline
- Evidence of adequate subject pool
- Maximin
- CONSORT list

### Challenges in RCTs of educational interventions

- Care as usual control
  - Roiland- What’s going on over there?
  - Quality of usual care can effect outcome of your study
  - The most common control group
- Care as usual on a waitlist
  - Good when follow-up period is short
  - Encourages subjects to join and stay on study
  - Increases cost

### Control groups cont.

- Attention
  - Almost impossible to have a placebo control
  - Controls for some non-specific factors
  - Common to use education about an unrelated topic

### Blinding

- Can’t double blind
- Can sometimes single-blind
- Can and should blind outcome data collectors to subject condition

### The Beginning