Palliative Care Research Cooperative Group: The Process of Intervention Development

a webinar in the Investigator Development series

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www.palliativecareresearch.org
Overview

1. A behavioral analysis of intervention development
2. Systematic approaches to intervention development
3. Intervention development: Two case studies
4. Conclusions
Duke Pain Prevention and Treatment Research Program

Our Research Program:
- Understanding adjustment to persistent disease-related
- Testing psychosocial protocols to reduce pain, disability, and distress
- Developing novel ways to deliver and disseminate psychosocial pain treatment protocols

Our Clinical Program:
Has played a key role in the development of a number of Duke Medical Center multidisciplinary pain management programs
Intervention Development: Drug Studies vs Behavioral Research
Intervention Development and Delivery

- Drug studies
- Behavioral studies
The Palliative Care Research Team: A Potentially Rich Source for Intervention Development
Intervention Development: A Behavioral Analysis
How many of you are confident that you can ride an “ordinary” the first time you try?
An “Ordinary”

Key problem in learning to ride an ordinary: Focusing on the outcome
The Outcome: “Taking a Header”
Problematic Thoughts, Feelings, and Behaviors
Taking a Header: Thoughts, Feelings, and Behaviors

Thoughts
- “I am a failure”
- “I’ll never learn to ride”
- “Everyone is laughing at me”
- “Riding an ordinary is stupid anyway, why bother?”

Feelings and Behaviors
- Shame
- Discouragement
- Isolation from others
- Procrastination
- Giving up
How many of you are confident you can develop an effective intervention the first time you try?
Key Problem: Focus on the Outcome
Problematic Thoughts, Feelings, and Behaviors

**Thoughts**
- “I will never be able to do this”
- “My ideas for an intervention are not good enough”
- “Even if I develop it, it won’t work”
- “No one understands how difficult this problem/population is”
- “It is too complicated and I will never be able to figure out where to start”
- “Doing intervention research is not that important to me anyway, so why bother?”

**Feelings and Behaviors**
- Shame
- Anxiety
- Discouragement
- Depression
- Isolation from others
- Procrastination
- Giving up
Should I Develop an Intervention?
A Thought Experiment
Option 1: Using an Established Intervention
Deciding to Use an Established Intervention

- When is it advantageous to use an established intervention?
  - When moving from one setting to another
  - When effective Tx are available already
  - When working in a different cultural population
  - When resources are limited

- What are the downsides of using an established intervention?
  - Not that innovative
  - May overlook essential features needed for success
  - May not work for some people
  - May have limited resources
Option 2: Developing Your Own Intervention
How big a step?

Ordinary Bicycle (1869)  
(Psychoanalysis)

Safety Bicycle (1887)  
(Cognitive Behavioral Therapy)
How big a step?

Safety Bicycle (1887) (Cognitive Behavioral Therapy)

Road Bicycle (2015) (Cognitive Behavioral Therapy App)
A Behavioral Analysis: Key Concept

*Intervention Development is a Skill*
Implications

- Learning how to develop interventions is a skill that can be learned like any other skill.
- Practice is essential in developing this skill.
- Mastering this skill can only come from developing (and revising) multiple interventions.
Systematic Approaches to Intervention Development
Examples of Systematic Approaches to Intervention Development

- Intervention Mapping
- Theory Informed-Implementation Intervention
- ORBIT Model for Behavioral Intervention Development
Intervention Mapping: A Process for Developing Theory- and Evidence-Based Health Education Programs

L. Kay Bartholomew, EdD, MPH
Guy S. Parcel, PhD
Gerjo Kok, PhD

The practice of health education involves three major program-planning activities: needs assessment, program development, and evaluation. Over the past 20 years, significant enhancements have been made to the...
Developing theory-informed behaviour change interventions to implement evidence into practice: a systematic approach using the Theoretical Domains Framework

Simon D French, Sally E Green, Denise A O’Connor, Joanne E McKenzie, Jill J France, Susan Michie, Rachelle Buchbinder, Peter Schattner, Neil Spike and Jeremy M Grimshaw


Table 1 Steps for developing a theory-informed implementation intervention

<table>
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<tr>
<th>Step</th>
<th>Tasks</th>
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| STEP 1: Who needs to do what, differently? | - Identify the evidence-practice gap  
- Specify the behaviour change needed to reduce the evidence-practice gap  
- Specify the health professional group whose behaviour needs changing |
| STEP 2: Using a theoretical framework, which barriers and enablers need to be addressed? | - From the literature and experience of the development team, select which theory(ies) or theoretical framework(s), are likely to inform the pathways of change  
- Use the chosen theory(ies) or framework to identify the pathway(ies) of change and the possible barriers and enablers to that pathway  
- Use qualitative and/or quantitative methods to identify barriers and enablers to behaviour change |
| STEP 3: Which intervention components (behaviour change techniques and mode(s) of delivery) could overcome the modifiable barriers and enhance the enablers? | - Use the chosen theory, or framework, to identify potential behaviour change techniques to overcome the barriers and enhance the enablers  
- Identify evidence to inform the selection of potential behaviour change techniques and modes of delivery  
- Identify what is likely to be feasible, locally relevant, and acceptable and combine identified components into an acceptable intervention that can be delivered |
| STEP 4: How can behaviour change be measured and understood? | - Identify mediators of change to investigate the proposed pathways of change  
- Select appropriate outcome measures  
- Determine feasibility of outcomes to be measured |
From Ideas to Efficacy: The ORBIT Model for Developing Behavioral Treatments for Chronic Diseases

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Figure 1. The ORBIT model for behavioral treatment development.
Intervention Development: Conceptual Background and Two Case Examples
Conceptual Background
Traditional Biomedical Model of Pain

- Pain is the result of injury/disease
- Amount of pain is proportional to injury or disease
- Treat injury/disease pain will be relieved

R. Descartes (17th Century)
Evolution of Pain Models

21st Century

The Pain Neuromatrix Theory

- Sensory inputs
- Visual and other inputs that influence cognitive interpretation
- Phasic and tonic cognitive-emotional inputs from brain
- Activity of body’s stress regulation systems
  - Produce pattern that evokes pain

Key Point: Thoughts, Emotions and Behaviors (Appraisals and Coping Efforts) Shape and Influence the Pain Experience
Pain Coping Skills Training

Pain Coping Skills Training → Thoughts, Emotions and Behaviors (Appraisals and Coping Efforts)

Improvements in Pain and Pain Related Outcomes
Case Example 1: A mHealth Video-Conferencing Based Pain Coping Skills Training for Stem Cell Transplant Patients
ORBIT: Behavioral Treatment Development

Figure 1. The ORBIT model for behavioral treatment development.
Intervention Development: Pain Coping Skills Training for Stem Cell Transplant Patients

Significant Clinical Question: Can we provide stem cell transplant patients with a behavioral pain interventions that is efficacious and effective?

ORBIT Phase 1: Definition & Design
   What is the problem?
   Consideration of unique population needs.

ORBIT Phase 2: Proof of Concept & Pilots
   Beta intervention development based on core intervention and unique needs
   Focus Groups / User Testing
   Pilot: Small RCT, feasibility, acceptability, and patient engagement

ORBIT Phase 3: Efficacy
   Larger trial forthcoming

ORBIT Phase 4: Effectiveness
   Larger trial forthcoming

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What is a Behavioral Pain Coping Skills Training Intervention?

- Use behavioral & cognitive skills to enhance patient’s self-management of pain.
  - Relaxation to decrease tension
    - Progressive Muscle Relaxation, Imagery, Mini-relaxation
  - Activity pacing
  - Pleasant activity planning
  - Cognitive restructuring of negative pain-related thoughts
  - Goal setting & problem solving

- Traditional Delivery
  - 8-12 sessions, 1 hour long each
  - Conducted at the medical center
  - Delivered by a psychologist or other behavioral pain expert
  - Referral to therapist, calls between patient & therapist, schedule of appointment, & then appointment
Phase 1: Defining **Unique Needs** of Stem Cell Transplant Patients

- Patients not able to come to the medical center for additional appointments
  - Risk of infections
  - Live far from medical center
  - Limited physical functioning and vigor

- Patients have limited time
  - Competing medical appointments
  - Daily health maintenance routine
  - Limited physical functioning and vigor
Phase 2: Proof of Concept
Concept Design & Development

- Brief Intervention
  » 6 sessions

- Accessible intervention
  » Mobile health technology to implement video-conferencing

- Selection of Empirically Supported Skills
  » Progressive muscle relaxation
  » Mini-relaxation & Imagery
  » Activity Pacing & Pleasant Activity Planning
  » Cognitive restructuring
  » Problem solving
  » Goal Setting
Phase 2: Proof of Concept & Pilots

Focus Groups

- Focus Groups Presenting to Patients
  » Bridge hospitalization & home
  » Meaningful activities and physical activities
  » Information from other transplant patients
  » Share and hear others stories

- Focus Groups Presenting to Providers
  » Bridge hospitalization & home
    – Create a connection to patients hospital care
    – Create a place for patients to hear from other patients
Phase 2: Pilots
User Testing of Developed Intervention

- 6 sessions
  - 1st in hospital
  - 5 by Skype on return home

- Website with social sharing and learning

- Incorporation of information directly from other patients

- User testing and further refinement
  - 7 patients with pain went through the developed intervention
Some Examples of Pain Coping Skills Training for Stem Cell Transplant Intervention Content
Phase 2 Focus Groups: Patients want to hear the stories and experiences of others and share their own
  • Use of website for learning and sharing
How some patients explain pain following their transplant...

- Many say that pain decreases with time, though others say that they continue to have pain.

- Some patients report pain prior to transplant (often from other treatments), while others report pain only following transplant.

- Patients report neuropathic pain (particularly in feet and hands), joint pain, mouth pain, back pain, arthritis pain, stiffness.

- Not all experience pain, but many do.
Some Common Activities that Patients Report Overdoing After Transplant

- Cleaning
- Chores, house maintenance
- Shopping
- Holiday preparation
- Traveling
- Spending time with kids, grandchildren
- Work
- Baking, cooking
- Yard work
- Walking
I want to get rid of this terrible pain.
Will this ever go away?
What are they going to find?
Something is wrong.
I feel like a burden to my family.
Why me?
How do I explain this to family?
This pain makes me so frustrated.
Neutral, Positive, & Helpful Pain Related Thoughts
Reported by other transplant patients

• This too shall pass.
• I am blessed.
• This is what it is.
• Fix what you can fix.
• This is my life right now.
What other transplant patients have done for pain management…

(always check with your medical team to make sure these are right for you)

- Heating pads
- Cold pads
- Warm towels on sore areas (Try putting towels, socks in microwave to warm up!)
- Using pillows as support, to encourage good posture
- Physical therapy, strengthening exercises
- Creams for sore areas
- Lidocain patches
- Rubbing/massaging sore areas
- Wearing socks and good shoes
- Using gel inserts for shoes
- Medication
Phase 2: Pilot of Small RCT

- Formal trial of the developed Pain Coping Skills Training Intervention

- We just finished recruitment with 36 participants
  - 18 received the intervention
  - 18 were in the control group

- We will be looking at the phase 2 pilot data to evaluate:
  - Phase 3: Effect Sizes & differences between groups in pain, pain disability, fatigue, physical disability, and activity levels
  - Phase 4: Feasibility, acceptability, and patient engagement and satisfaction
What is next for this mobile pain coping skills intervention for stem cell transplant patients?

- **Phase 3: Efficacy**
  - Larger trial
  - mPCST compared to active intervention
  - Looking at wider range of outcomes

- **Phase 4: Effectiveness**
  - Can patients use their own mobile health devices?
  - Increased measurement of use of website
Case Example 2: Developing an Internet Based Intervention for Delivering Pain Coping Skills Training
Face to Face vs Internet Based Coping Skills Training

- Face to face training
  - Pros
    » Easy to personalize
    » Supportive therapist
  - Cons
    » Few trained therapists
    » Time

- Internet-based training (no therapist)
  - Pros
    » Build on empirically strong program
    » Reduced cost
    » 24/7 access
  - Cons
    » May not appeal to all
    » Adherence
Phase 1: Define and Refine PCST for Internet Delivery

- Key resources
- Treatment manual
- 4 PCST trainers >90 years experience delivering face to face treatment

- Step 1: Leverage resources
- Weekly meetings
- Screen by screen planning of program
- Layout content and functions
Today's Messages

Logging your practices in COACHtrack can help you stay on track. And logging your practices helps your coach give you personalized feedback on how you're doing in each session.
Challenge: How to Establish Therapeutic Alliance

- Virtual coach
- Tailored responses
- Manner
  - Conversational, empathic, warm
  - Body language changes to reflect content
Challenge: Skills Practice

- Behavioral rehearsal: emphasized face to face PCST
- PainCOACH
  - Guided practice
  - Characters discuss their reactions
  - Examples
Think about what position your body was in.
Tell me how you felt during your progressive relaxation by dragging the "More", "Less" or "No Change" options to each experience.

Relaxed: More
Happy: Less
Calm: Less
Clear-Headed: Less
Energetic: No Change
Heaviness: More
Warmth: Reset

Sleepy: Less
Pain: Less
Stiffness: Less
Muscle Tension: Less
Nervous: No Change
Frustrated: Less
Fidgety: Less

Reset | I'm Done
Challenge: What if Patient Had Problems Learning A Skill?

- Often seen in face to face sessions
- Development team identified list of common problems and concerns
- Team brainstorms strategies to deal with/prevent problems
- Use virtual coach
Sometimes when people practice progressive relaxation, they have some concerns or problems.
Solutions to Common Problems

Have you experienced any of these problems while doing your practices?

- I have muscle cramps or pain
- I fidget or can't sit still
- I'm distracted by noise
- I have muscle spasms and tics
- I can't stop my thoughts
- I fall asleep
- I cough and sneeze
- I feel uncomfortable
- I feel like I'm not in control
Self Monitoring

- COACHtrack:
- Participants log practice and goals
- Log entries used to tailor messages

- Badges awarded for accomplishments
- Interactive exercises to review practice
B1: Mini-Practices: Where Were You?

Touch each place where you had a good experience with mini-practices last week.

- Doctor's Office
- Store
- Work
- Place of Worship
- Bank
- Someone else's house

- Family Room
- Bedroom
- Kitchen
- Dining Room

- Your car
- Your Yard
- Park

I'm Done
Phase 2: Proof of Concept and Pilots
User Testing

- Method:
  - N=49 participants (mean age=67)
  - Diverse (55% women, 49% minority, mixed education and computer experience levels)
- General introduction to PainCOACH & review 4 sessions
- Individual meeting with RAs

- What they liked
  - Learning skills
  - Virtual Coach
  - Learning about others experiences
- What they felt needed work
  - Redesign of home screen
  - Eliminate need for typing
  - Reduce text and make it larger
Pilot Testing

- 8 participants used working prototype
- Provided feedback on technical problems and anything difficult, confusing, frustrating
- Given notebook with screenshots to take notes

- Phone interviews
- What they liked
  » Easing to log in
  » Easy to use
  » Skills important
  » Exercises/stories
- What they felt needed work
  » Audio download speed
Phase 3: Feasibility and Efficacy Trial
Design and Results

- **Study design**
  - N=113 patients with osteoarthritis pain
    - PainCOACH
    - Assessment only

- **Results:**
  - Significant reduction in pain in women
  - Effects could not be tested in men (very low pain level)

- **Both men and women improved:**
  - Self-efficacy
  - Anxiety
  - Pain interference
  - Negative affect
  - Positive affect

- **Acceptability**
  - 91% complete all 8 modules
PainCOACH Content

- Felt like the coach understood me: 71%
- Helped me with difficulties using skills: 86%
- Convinced me PCST important: 96%
- Hearing others' experiences useful: 86%
- Exercises helped me understand: 86%
- Information in sessions was useful: 96%

Strongly Agreed
Somewhat Agreed
Neither Agree nor Disagree
Somewhat Disagree
Strongly Disagree
Future Directions

- Refine PainCOACH based on RCT findings and conduct larger trial to move PainCOACH toward dissemination
Collaborators and Funding

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Conclusions
Conclusions

1. Intervention development is a skill
2. New interventions can be “little steps”
3. Formal models are available to guide intervention development
4. Clinical experience and the ability to work with teams are key skills in developing and refining an intervention
Thank you for joining the webinar

• Send any remaining questions to Sarah Garrigues via the WebEx chat function or email: sarah.garrigues@ucsf.edu

• Please complete the evaluation via email

• Join us for the next webinar in the Investigator Development Series: Developing a Budget for Multi-Site Studies
  Drs. Kutner & Ritchie
  October 16, 2015
  Visit the website for details