



PALLIATIVE CARE
RESEARCH COOPERATIVE



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

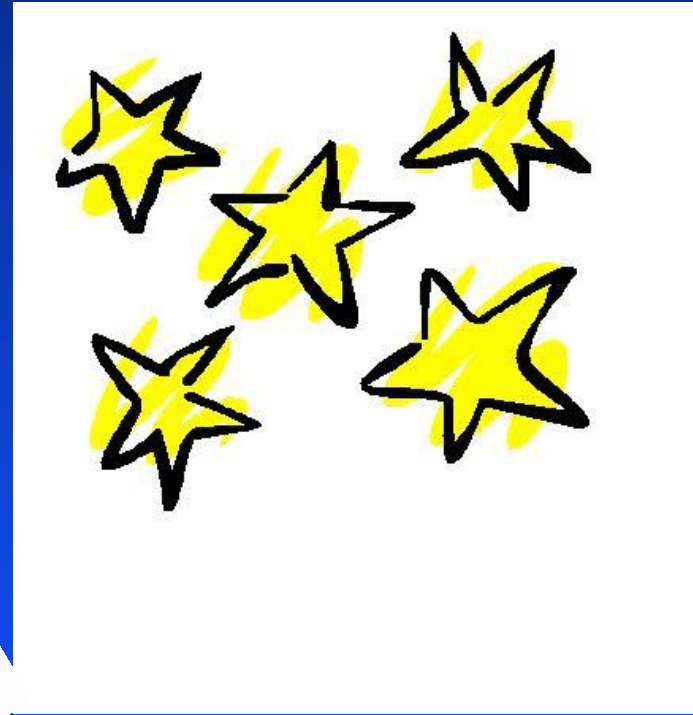
How many of you are confident
that you can ride an “ordinary”
the first time you try?

An “Ordinary”



Key problem in learning to ride an ordinary: Focusing on the outcome

The Outcome: "Taking a Header"



Problematic Thoughts, Feelings, and Behaviors

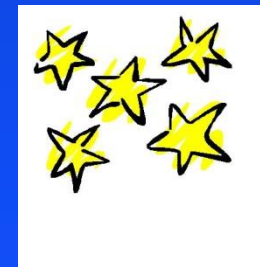
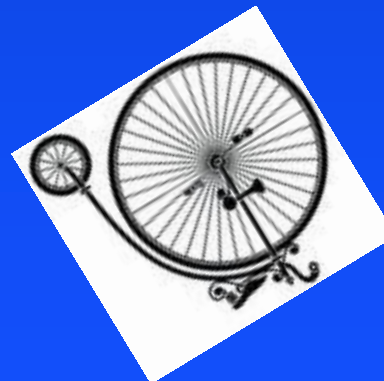
Taking a Header: Thoughts, Feelings, and Behaviors

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

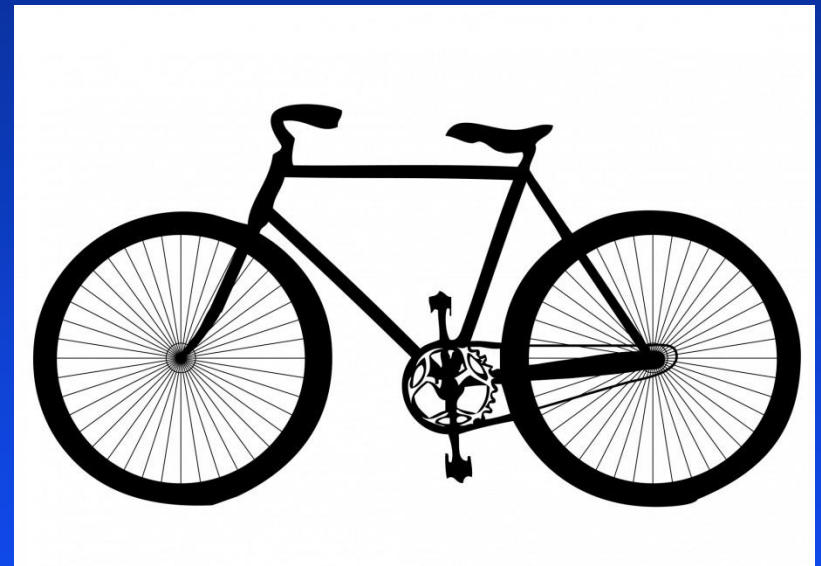


How big a step?



Ordinary Bicycle (1869)

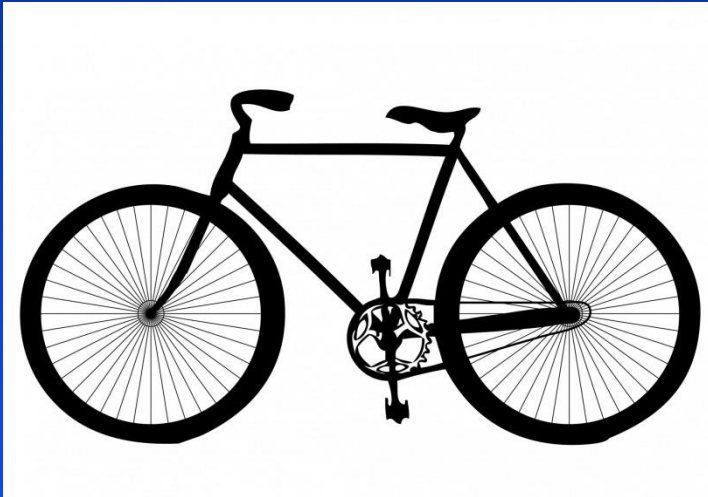
(Psychoanalysis)



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

Bartholomew et al. (1998)

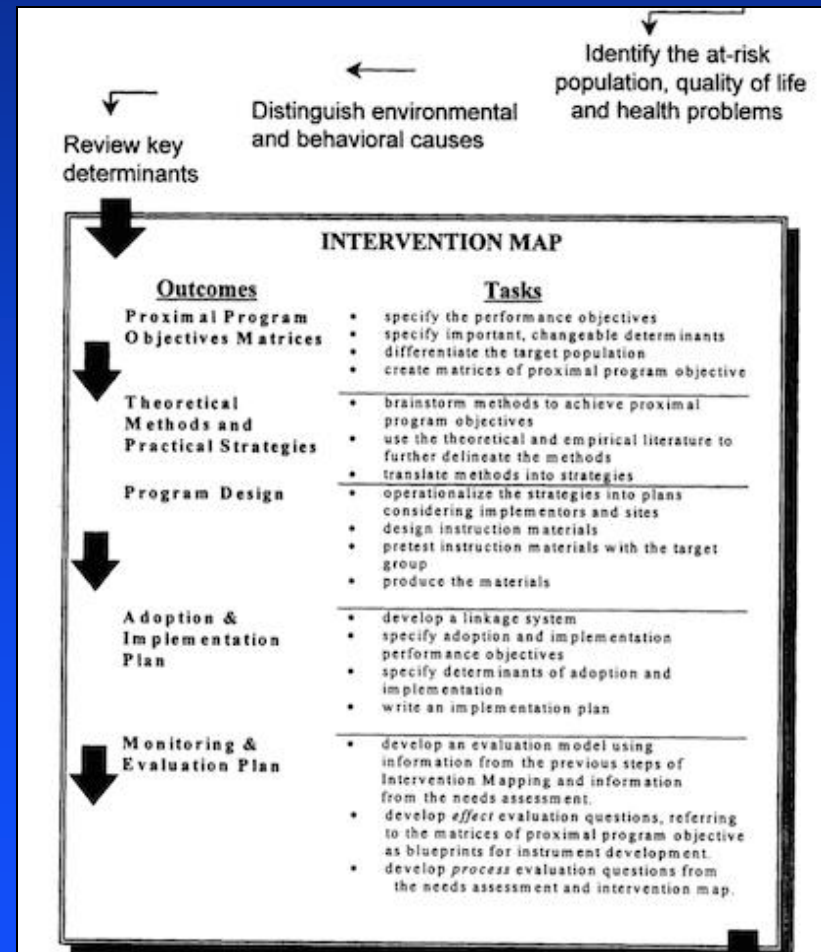
Intervention Mapping: A Process for Developing Theory- and Evidence-Based Health Education Programs

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



Theory-Informed Behaviour Change Interventions

French et al. *Implementation Science* 2012, **7**:38
<http://www.implementationscience.com/content/7/1/38>



METHODOLOGY

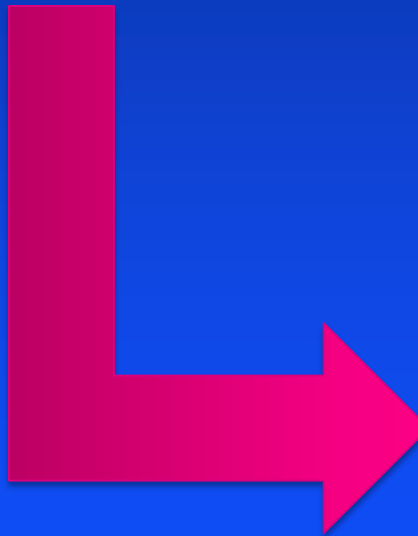
Open Access

Developing theory-informed behaviour change interventions to implement evidence into practice: a systematic approach using the Theoretical Domains Framework

Simon D French^{1,2*}, Sally E Green¹, Denise A O'Connor¹, Joanne E McKenzie¹, Jill J Francis³, Susan Michie⁴, Rachelle Buchbinder^{1,5,9}, Peter Schattner⁶, Neil Spike⁶ and Jeremy M Grimshaw^{7,8}

Table 1 Steps for developing a theory-informed implementation intervention

Step	Tasks
STEP 1: Who needs to do what, differently?	<ul style="list-style-type: none"> • 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?	<ul style="list-style-type: none"> • 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(s) 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?	<ul style="list-style-type: none"> • 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?	<ul style="list-style-type: none"> • Identify mediators of change to investigate the proposed pathways of change • Select appropriate outcome measures • Determine feasibility of outcomes to be measured



ORBIT Model for Behavioral Treatment Development

Health Psychology © 2015 American Psychological Association
0278-6133/15/\$12.00 <http://dx.doi.org/10.1037/hea0000161>

From Ideas to Efficacy: The ORBIT Model for Developing Behavioral Treatments for Chronic Diseases

Susan M. Czajkowski* Lynda H. Powell*
National Heart, Lung, and Blood Institute, Rush University Medical Center, Chicago, Illinois
National Institutes of Health, Bethesda, Maryland

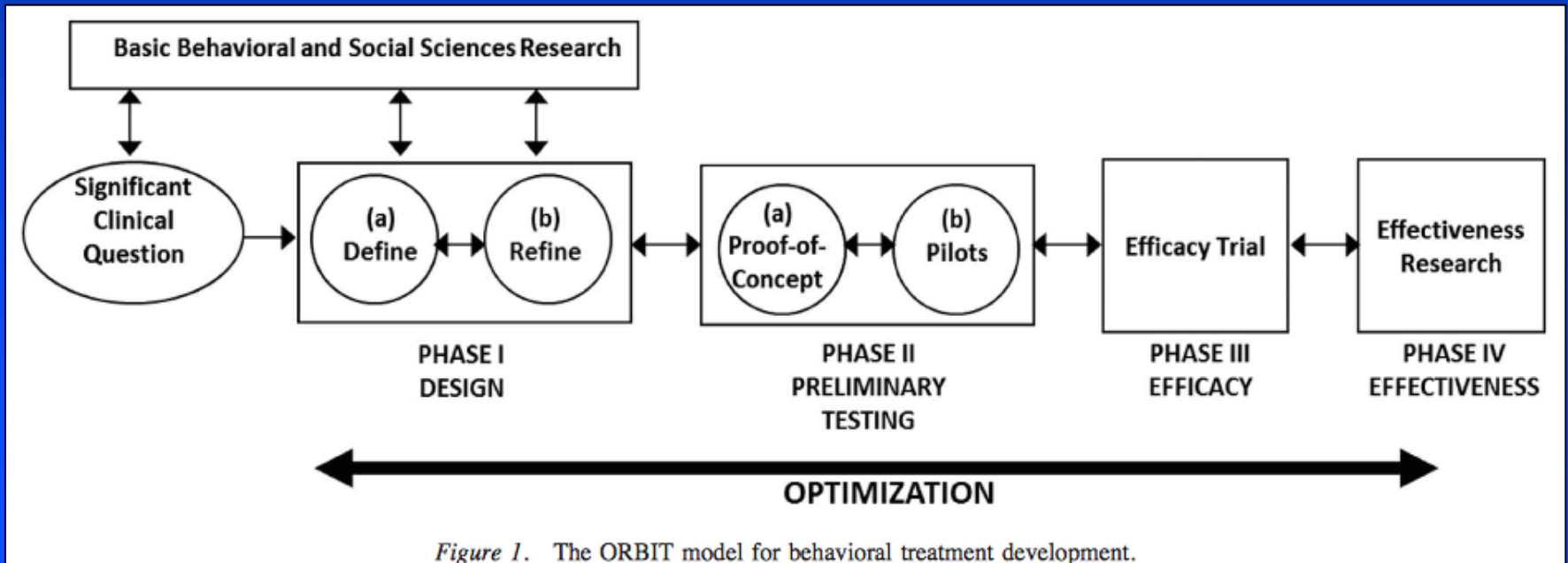


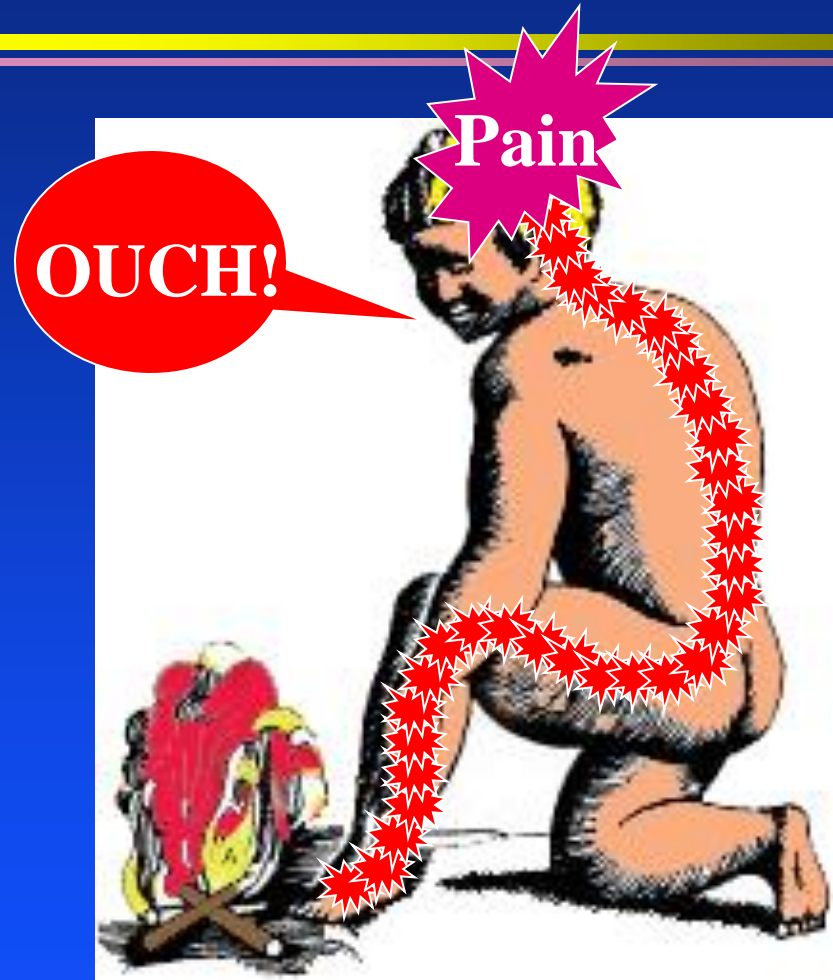
Figure 1. The ORBIT model for behavioral treatment development.

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

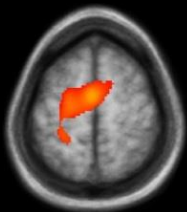


21st Century

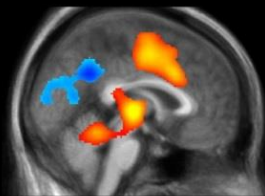


The Pain Neuromatrix

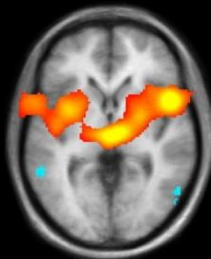
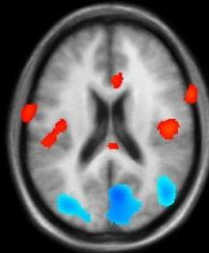
PRIMARY
SOMATOSENSORY
CORTEX



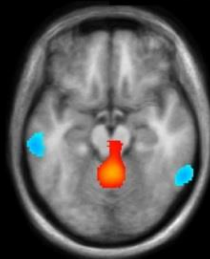
ANTERIOR
CINGULATE
CORTEX



SECONDARY
SOMATOSENSORY
CORTEX



ANTERIOR
INSULA



CEREBELLUM

Coghill et al. J. Neurophysiology 1999

The Neuromatrix Theory

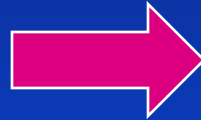
- » Sensory inputs
- » Visual and other inputs that influence cognitive interpretation
- » Phasic and tonic cognitive-emotional inputs from brain
- » Activity of body's stress regulation systems

- 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

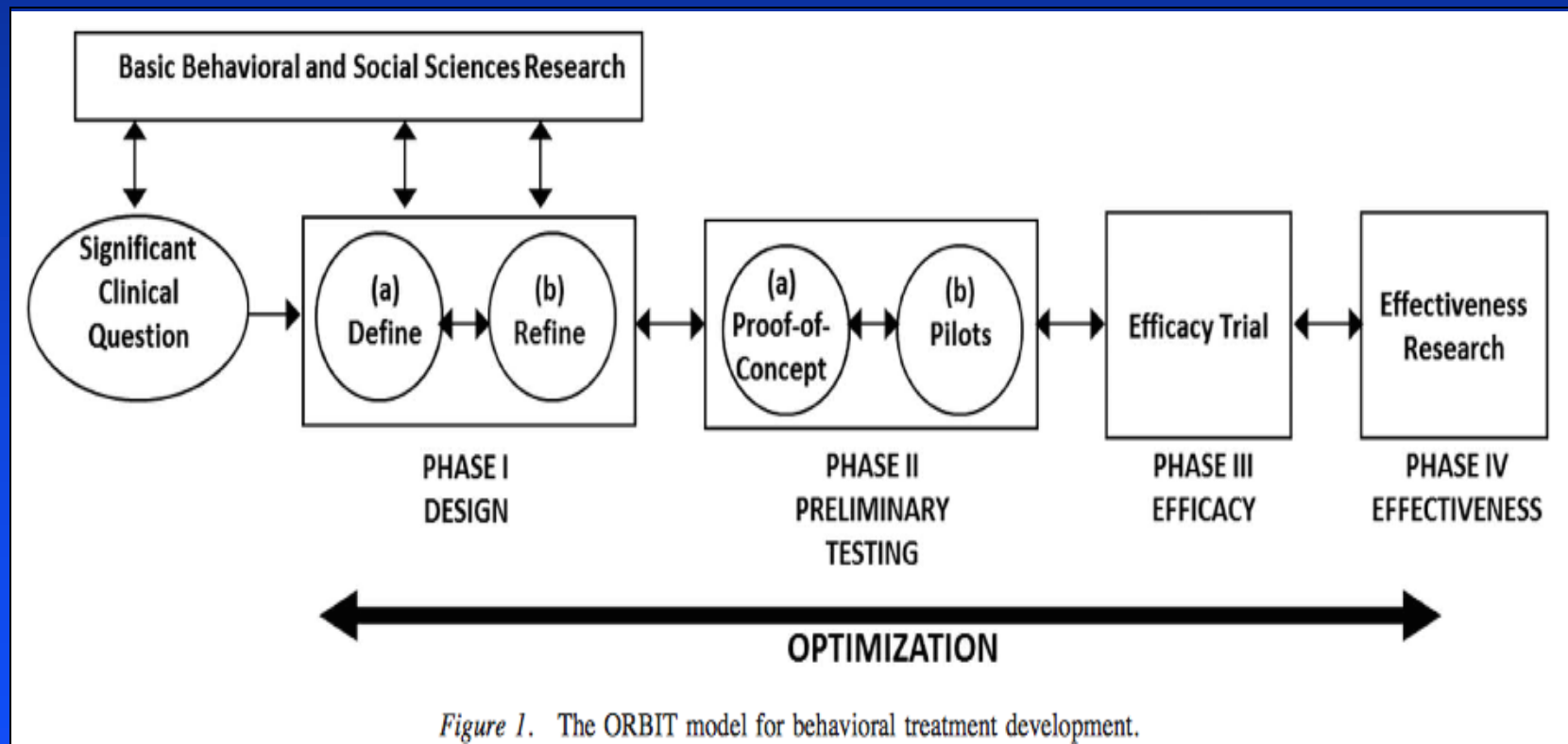


Figure 1. The ORBIT model for behavioral treatment development.

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

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

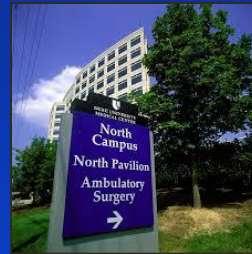
Focus Groups

- 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



Bridges Hospitalization & Home



Some Examples of Pain Coping Skills Training for Stem Cell Transplant Intervention Content

Pain Coping Skills Training for Patients Following Transplant

- **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



DukeMedicine

I-CAN

improving cancer pain management
a program for patients with pain

Questions

Muscle Relaxation

Video

Sharing

Skype

Session Information

Share your I-CAN thoughts and experiences.

Please do not include information in your response that would identify you such as name, email or hometown.

What benefits have you found from practicing progressive muscle relaxation and/or mini practices? [Share](#)

[Read others comments](#)

How have you found time to regularly practice progressive muscle relaxation and/or mini practices? [Share](#)

[Read others comments](#)

What benefits have you found from using imagery? [Share](#)

[Read others comments](#)

How have you used imagery? [Share](#)

[Read others comments](#)

What activities are you more successful doing with the use of activity rest cycling? [Share](#)

[Read others comments](#)

What are some of the pleasant activities you have either added to your list or participated in? [Share](#)

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

Unhelpful Pain Related Thoughts

Reported by other transplant patients

- 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



PainCOACH

 Test Connection

 Logout



Sessions



1: Understanding Pain and Relaxation



2: Brief Relaxation with Mini-Practices



3: Activity/Rest Cycles



4: Pleasant Activity Scheduling



5: Coping Thoughts



6: Pleasant Imagery



7: Problem Solving

8: Looking Back and Moving Forward

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.

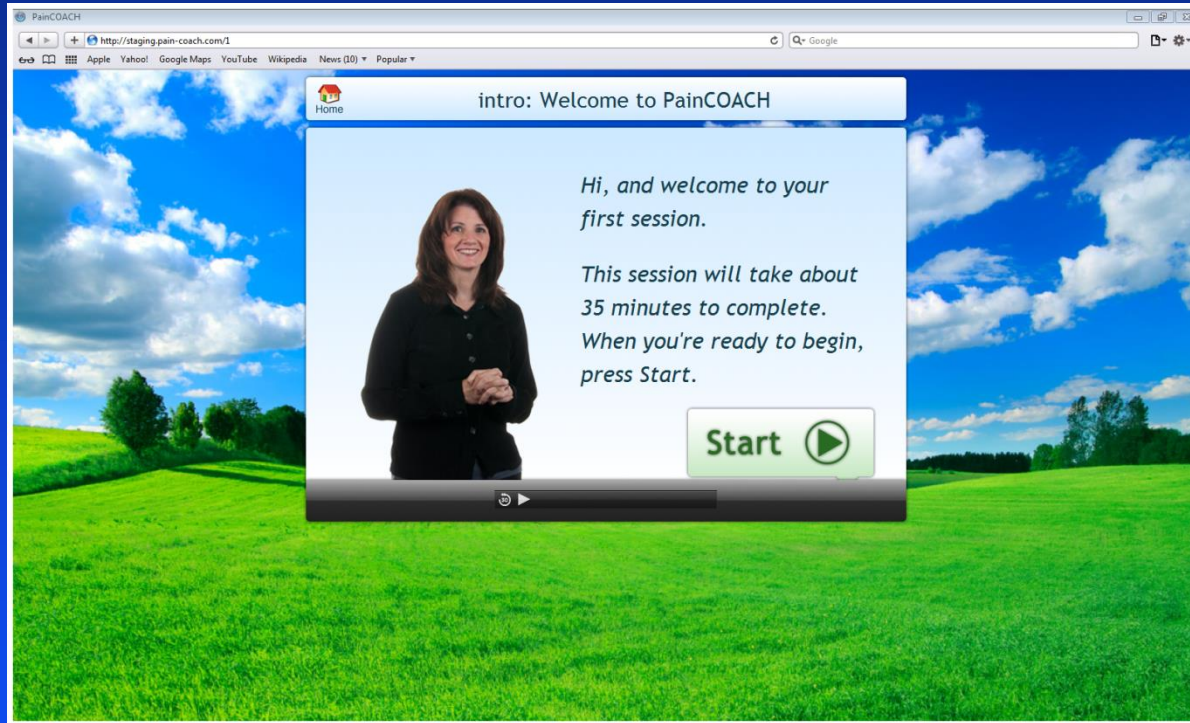
[Next Message](#)

▶ [COACHtrack](#)

▶ [COACHchat](#)

▶ [MyCOACH](#)

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





Home

Progressive Relaxation: How Did You Feel?



Think about what position your body was in.

Restart

Pause ||

< Back

Next >



Progressive Relaxation: How Did You Feel?

Tell me how you felt during your progressive relaxation by dragging the "More", "Less" or "No Change" options to each experience.

Relaxed	<input type="button" value="More"/>	<input type="button" value="More"/>	Sleepy	<input type="text"/>
Happy	<input type="text"/>		Pain	<input type="button" value="Less"/>
Calm	<input type="button" value="More"/>	<input type="button" value="Less"/>	Stiffness	<input type="text"/>
Clear-Headed	<input type="text"/>	<input type="button" value="No Change"/>	Muscle Tension	<input type="button" value="Less"/>
Energetic	<input type="text"/>		Nervous	<input type="button" value="No Change"/>
Heaviness	<input type="button" value="More"/>		Frustrated	<input type="text"/>
Warmth	<input type="text"/>	<input type="button" value="Reset"/>	Fidgety	<input type="text"/>
		<input type="button" value="I'm Done"/>		

Restart

Pause



Back

Next

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





Home

Solutions to Common Problems

Sometimes when people practice progressive relaxation, they have some concerns or problems



Restart

Play ▶

Loading audio...

◀ Back

Next ▶



Home

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

Restart

Pause ||



< Back

Next >

Self Monitoring

- COACHtrack:
- Participants log practice and goals
- Log entries used to tailor messages
- Badges awarded for accomplishments
- Interactive exercises to review practice



Home

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



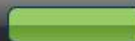
Someone else's house



I'm Done

Restart

Play ▶



0:10



◀ Back

Next ▶

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

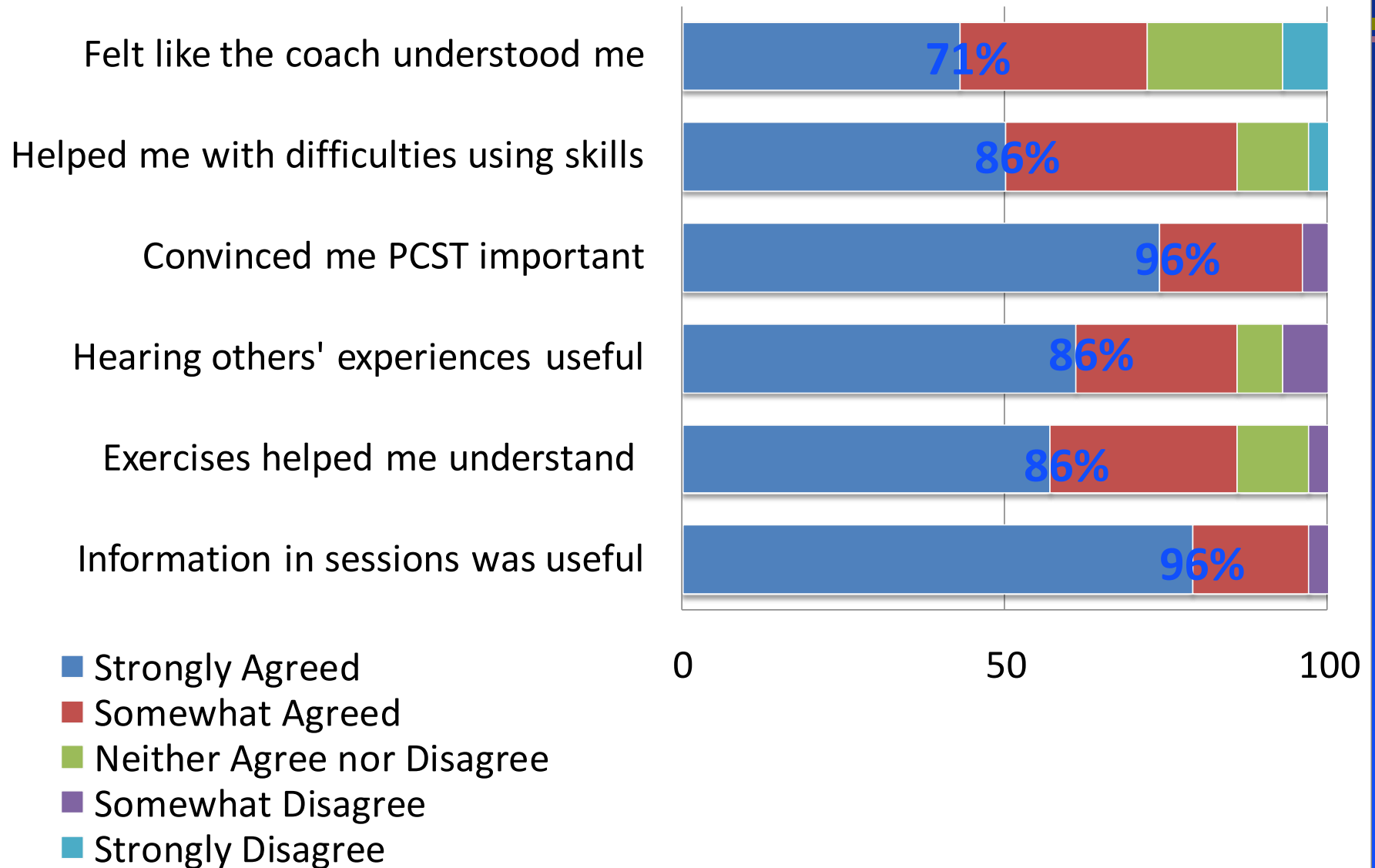
- 8 participants used working prototype
- Provided feedback on technical problems and anything difficult, confusing, frustrating
- Given notebook with screenshots to take notes
- Phone interviews
- What they liked
 - » Easing to log in
 - » Easy to use
 - » Skills important
 - » Exercises/stories
- What 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



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

 palliativecareresearch.org

 [@pcrcgroup](https://twitter.com/pcrcgroup)

 [pcrcgroup](https://www.facebook.com/pcrcgroup)

 pcrc@duke.edu

