

Nursing Intervention Development Research

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Today

- Introduction: What is intervention development research, define key terms
- Examples from our work intervention development at different stages & using different approaches
 - ❑ C. Genest (mental health)
 - ❑ M. Berube (trauma care)
 - ❑ S. Lambert (oncology)
 - ❑ N. Feeley (NICU)

Interventions ... (Sidani & Braden 2011)

- Have **components** = an inter-related set actions directed towards an aspect of the identified problem or desired outcome
- Differ in level of **complexity**: from **simple single** actions/components to **multi-components** targeted at different levels or aspects of the problem

5 phases of nursing clinical trials (Whittemore & Grey 2002)

Based on US National Institutes of Health phases of clinical trials

Phase	Goal	What is done
I	Establish content, strength, timing Rx & outcomes	Intervention development research <ul style="list-style-type: none">• Use multi methods• Involves synthesis of evidence, theory, clinical knowledge
II	Refine Rx & outcomes	Pilot study <ul style="list-style-type: none">• Feasibility• Preliminary effect size
III	Determine efficacy	RCT
IV	Determine effectiveness	RCT in actual real practice
V	Determine effect on public health	Wide scale implementation

The goal of intervention development is to operationalize the intervention/ program so that it can be assessed for feasibility/acceptability, efficacy, and effectiveness.



Process of intervention development: Address decisions about these elements

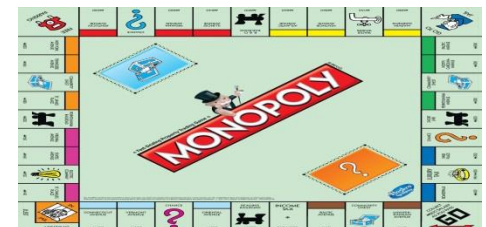
- **What** should be done (*content*)
- **When** (*timing*)
- **How much** (*dose, frequency, duration*)
- **Where**
- **How** (*mode(s) of provision: booklet, face to face*)
- **Who will provide** RX
- **Who will be participate** in RX

In past ...

- Any idea of what might work: “Let’s try this and that ...”
- Assumed feasible & acceptable, no piloting but proceed right to trial

& now...

- Evidence-based content & format +
- Patient engagement in Rx design
- Pilot study to examine feasibility & acceptability examined
- Only then do you proceed to trial



Intervention development: NOW



- Systematic
- Requires comprehensive knowledge of current evidence on
 - **Clinical problem** & aspects of it amenable to change
 - **Theories** about problem & mechanisms
 - Possible **efficacious RX** components
- Deductive & inductive approaches
- Use of multiple methods



QUAL & QUANT

Designing an intervention: Determine the elements (Sidani & Braden)

Three ways:

1. Theory based
2. Empirical
3. Experiential

Designing an intervention: Determine the elements

1. Theory based:

- **Middle range theory used** explains problem, factors & consequences, relationships among factors, problem & outcomes and/or
- **Practice or prescriptive theories used** to determine intervention components, mode of delivery, dose, frequency, duration
- **PROS:** guide what is important target, evidence indicates theory-based Rx more effective
- **CONS:** ? Is it comprehensive (includes all relevant factors), may not be empirically supported, may not be best fit (“forcing”)

Designing an intervention: Determine the elements

2. Empirical:

- Use evidence about **problem & interventions** from **reviews** of evidence or individual **studies** if no review (correlational, longitudinal & RCTs)
- **PROS:** grounded in evidence
- **CONS:** no patient engagement. ? Feasibility & ? acceptability

Designing an intervention: Determine the elements

3. Experiential:

- Target population and/or clinicians participate in design through:
 - **Focus groups:** describe problem & determinants & ask them to identify determinants they experience, could modify, strategies use, which are feasible
 - **Survey** on preferences of individuals/groups: list strategies & rate utility to address problem, feasibility of utilizing or describe RX & rate how appropriate is, indicate preferred modes, dose
 - **Pre-test:** a few target participants “pilot of your pilot RX”
- **PROS:** high acceptability
- **CONS:** time required, biased by views participants if small number

Recommendations (Sidani & Braden)

- Each approach has PROS & CONS
- Best use combination in developing Rx that is both evidence based & acceptable to recipients
- **USE sequential application of 3 approaches**



Step 3: Experiential

Step 2: Empirical

Step 1: Theory-based

Recommendations

Systematic development of efficacious & effective nursing interventions
(Whittemore & Grey 2002)

Synthesize knowledge from these sources

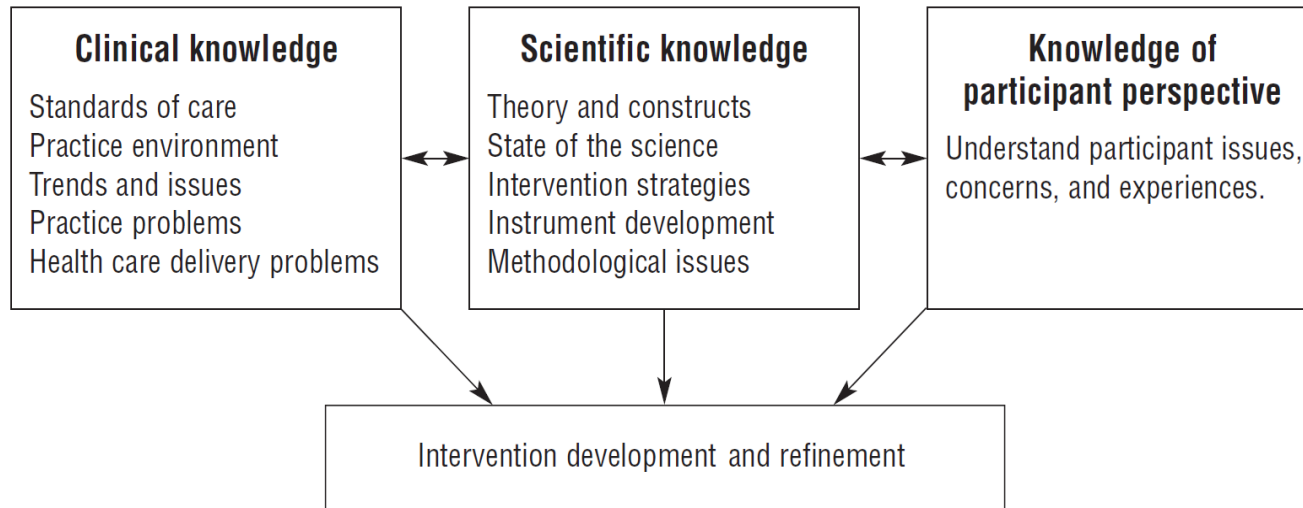
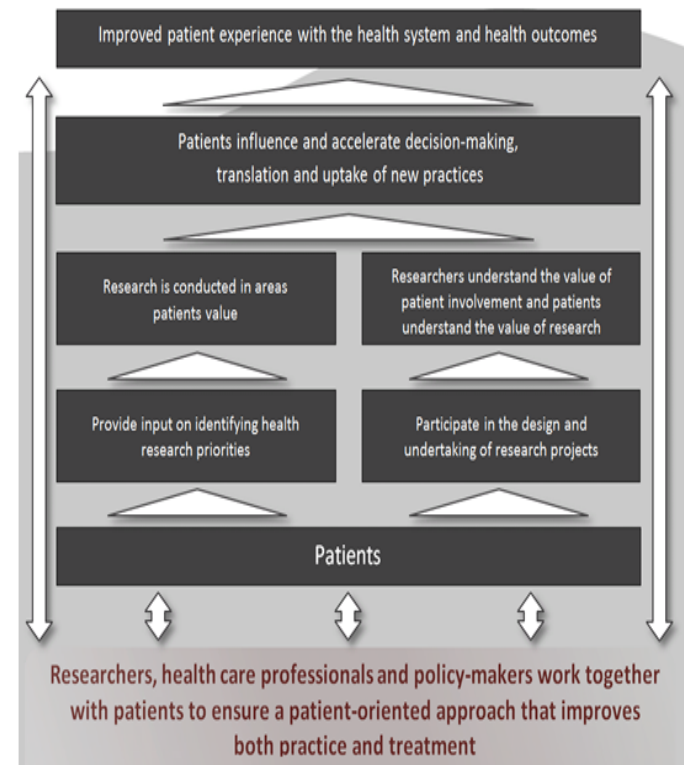


Figure 1. Multiple perspectives in intervention development.

Patient-oriented research essential

CIHR

- ***“Patients must be involved as much and as meaningfully as possible in order for health research to be more responsive to the needs of Canadians.”***
- Patients bring perspective as ‘experts’ from their unique experience & knowledge gained through living with a condition & experiences with health care system.
- Involvement increases quality of research & care
- Patient-oriented research is ultimately aimed at achieving benefits that matter to patients





EXAMPLES OF INTERVENTION DEVELOPMENT IN ACTION

- ❑ E-intervention fostering post-traumatic growth in suicide survivors
- ❑ **iPACT-E-Trauma: Rx to Prevent Acute to Chronic Pain Transition Extremity Trauma Patients**
- ❑ **Coping together for cancer caregivers**
- ❑ **Cues: Reducing anxiety & promoting sensitivity in mothers of preterm infants**

Process of developing E-intervention fostering post-traumatic growth of suicide survivors

Problem	Suicide survivors at risk of depression, anxiety, PTSD and suicide ideation Post-traumatic growth (PTG) concept developed by Tedeschi and Calhoun (1996)
Approach(es) to intervention development	Empirical approach : Literature review on interventions fostering PTG and interventions targeting suicide survivors Experiential approach : suicide survivors and professionals working with them to address their needs and the feasibility of the proposed intervention.
Methods used	Semi-structured interviews with suicide survivors Focus groups with professional
Challenges in process of development	Recruitment of the survivors and identification of the target population Identification of an existing intervention to build on
Solutions	Looking more broadly at interventions fostering PTG in other population
Lessons learned	Think in terms of feasibility of the future pilot study or eventually RCT Work in team with members of the target population.

Time line/phases

E-intervention fostering post-traumatic growth of suicide survivors

Problem identification

Literature review on PTG and intervention for suicide survivors

Suicide survivors needs identification

Pilot study

Professional focus group on the feasibility of the intervention

To be presented to survivors and professionals

What should be done (content)	CBT online
When (timing)	Few months after the traumatic experience
How much (dose, frequency, duration)	5 weeks, 2 weekly writing assignments. 3 treatments phases with psycho-education at each phase (self-confrontation, cognitive reconstruction and social sharing or farewell ritual)
Where	Home
How (mode: app, face to face)	Email, online learning
Who will provide RX	Nurses or skill professional who know CBT
Who will be participate in RX (target clientele)	Suicide survivors scoring on PTSD

Intervention visant à prévenir
la douleur chronique
suite à un traumatisme
orthopédique aux extrémités

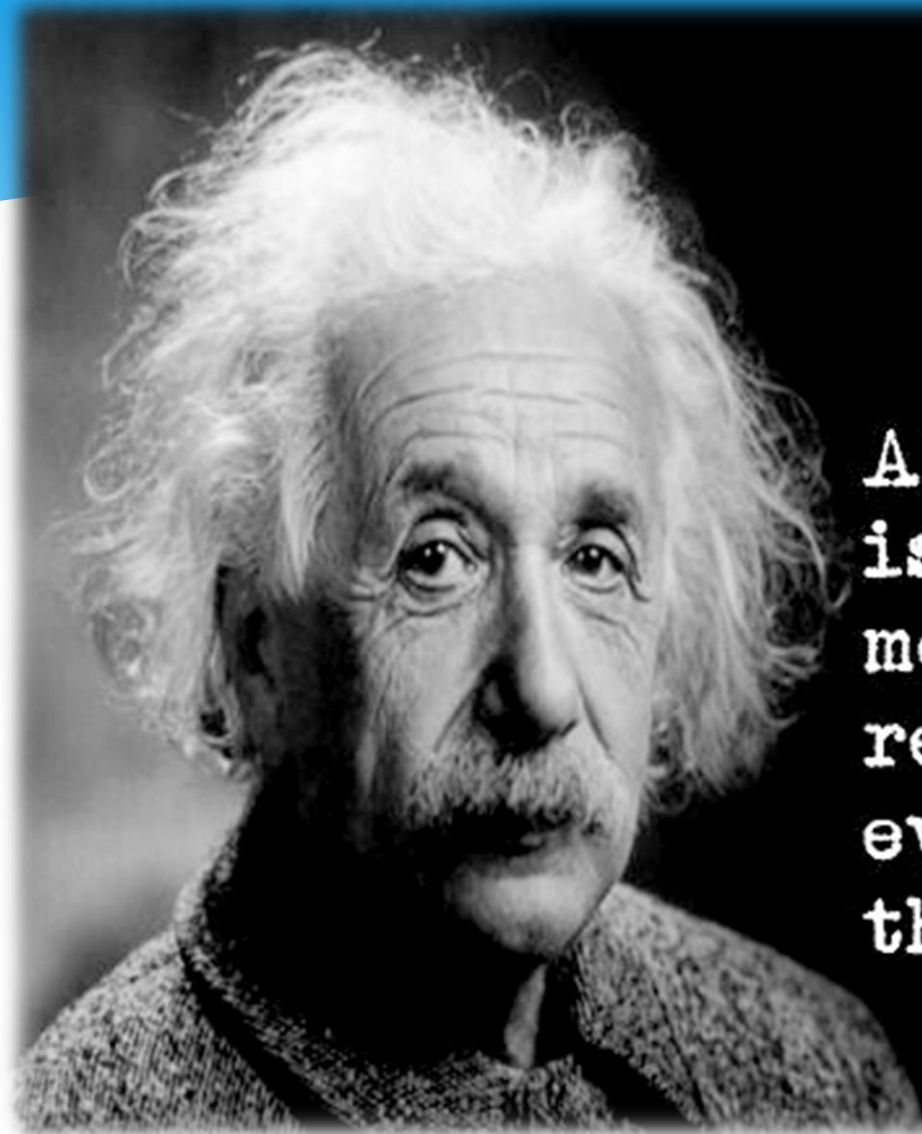


iPACT-E-Trauma



Process of developing iPACT-E Trauma

Problem	<ul style="list-style-type: none"> • Acute pain converts to chronic pain in up to 86% of ET patients • The development of chronic pain is caused by complex interactions between biopsychosocial factors
Approach(es) to intervention development (Sidani & Braden, 2011)	<p>Empirical:</p> <ul style="list-style-type: none"> • Longitudinal studies and systematic reviews on chronic pain risk factors and protective factors • Systematic reviews on chronic pain interventions • RCTs on chronic pain preventive interventions <p>Clinical knowledge???</p> <ul style="list-style-type: none"> • When to initiate the intervention, content, order of content delivery and sequence of sessions taking into account the typical continuum of care
Methods used	<p>Clinicians:</p> <ul style="list-style-type: none"> • Survey with the Treatment Acceptability and Preference (TAP) questionnaire • Focus group <p>Patients:</p> <ul style="list-style-type: none"> • Pre-test with 6 patients • Survey with the TAP questionnaire along intervention delivery
Challenges in process of development	<ul style="list-style-type: none"> • Trauma patients are very heterogeneous • Plan sessions delivery according to patients average LOS, the place where they are discharged and the timing of their medical follow-up in outpatient clinic • Ensure that sessions length and content respect patient attention span while being hospitalized in acute care settings
Solutions	<ul style="list-style-type: none"> • Establish a flexible plan, consult clinicians and pre-test the intervention
Lesson learned	<ul style="list-style-type: none"> • Seeing intervention development as a work in progress



All of science
is nothing
more than the
refinement of
everyday
thinking.

- *Albert Einstein*

www.quotesworthrepeating.com

iPACT-E-Trauma

Ultimate goal (problem resolution):

Prevent acute to chronic pain transition at 6 months post-injury in major lower ET patients
(reduce pain intensity and pain interference with activities and maintain scores < 4/10)

Immediate goals:	Components: (content):	Activities: (content):	Dose: (How much, where, timing):	Modes of delivery: (How):
Increase chronic pain protective factors and decrease risk factors.	1-Biopsychosocial dimensions of pain; 2-Pharmacological and non-pharmacological pain management strategies; 3- Health promotion strategies; 4- Return to pre-injury activities.	<ul style="list-style-type: none"> - Education - Relaxation skills - Problem solving - Graded activities - Activity pacing - Situation matching - Continued monitoring - Feedback provision 	<ul style="list-style-type: none"> - 5 weekly 15-30 minutes sessions beginning during hospitalization - 2 booster 15 minutes sessions (last session at 3 months) 	<ul style="list-style-type: none"> - Web (first 3 sessions in hospital) - Telephone or face to face (total of 4 sessions)

• C'EST LA
PREMIÈRE FOIS.

melanietest

●●●●●●●●



• VOUS AVEZ OUBLIÉ VOTRE MOT DE PASSE.



Soulage TAVIE post-trauma

*Une intervention virtuelle pour
prévenir la transition de la douleur
aiguë à chronique*



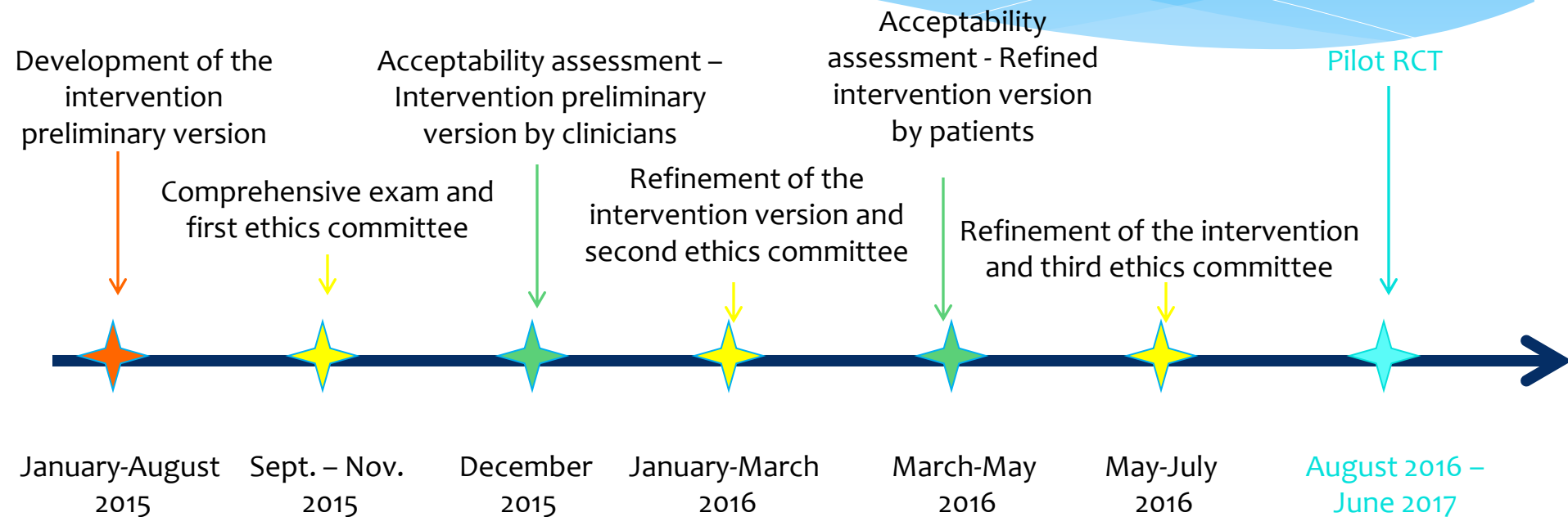
Pour profiter pleinement du site, un ordinateur et un des navigateurs suivants sont nécessaires: Firefox (dernière version), Chrome (dernière version).

• CRÉDITS

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Time line of developing iPACT-E-Trauma



Development phase = 21 months

coping together



Process of developing



Problem	Lack of formal training and support to informal cancer caregivers
Approach(es) to intervention development	<p>Empirical: 1) Large, longitudinal study examining the predictors of caregivers' needs, anxiety, and depression (included coping, social support), 2) Meta-analysis of existing caregiver interventions to further define content and effective (or 'active') elements (e.g., skills training essential, including problem-solving and communication skills), and 3) Systematic review of studies examining caregivers' unmet needs</p> <p>Theory-based: 1) Lazarus & Folkman's Stress and Coping Theory to define the mechanisms of action of the intervention, 2) Dyadic Coping Theory to support focusing on the patient-caregiver pair, and 3) Social Cognitive Theory to guide our approach to learning</p> <p>Clinical knowledge: Clinicians identify content and coping skills</p> <p>Experiential: Pre-tested the intervention early on with patients and their partners to obtain feedback on the booklets' appropriateness and willingness to use this type of resource to cope with cancer challenges</p>
Methods used	Longitudinal study, systematic review, qualitative pre-test (iterative process), then pilot RCT, and large RCT
Challenges in process of development	1) Recruitment, 2) self-directed format overcome many barriers to access and sustainability, but then use and adherence become an issue, 3) working with graphic artist and designer, 4) choosing which content to focus on to avoid cognitive overload
Solutions	1) Strong partnerships, 2) paying attention to how adults learn, how the information is presented, when, why..., 3) work with experienced graphic artists, 4) keep goals in mind and pre-test intervention
Lessons learned	Integrate principles of adult learning, finish pilot before embarking on larger trial, take time to market the intervention

Phases: coping & together

Phase 1 - Began development of *Coping-Together* and qualitative acceptability study

Phase 2 - Funding - Clinical Oncological Society of Australia (COSA) - Pilot

Phase 3 - Funding - NHMRC Project Grant

Phase 2 - COSA Pilot resource finalised and recruitment commenced

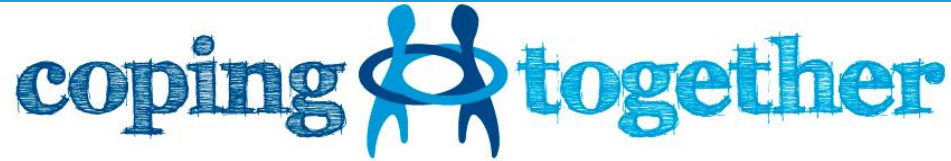
Phase 3 - Begin recruitment

Phase 4 - Prostate Cancer Canada Funding to develop online version

Phase 5 - Adaptation to caregivers with advanced cancer



Barriers	Strategies to overcome or minimize barriers
No time	<ul style="list-style-type: none"> - Concise presentation of information (preferably point form) - Tailor to make it more relevant to patients and partners (e.g., by cancer type) - Small booklets so able to take to appointments, on the train - Provide an initial workshop or orientation session
Too ill	<ul style="list-style-type: none"> - Provide an initial workshop or orientation session - Use a DVD instead of print
Too stressed	<ul style="list-style-type: none"> - Concise presentation of information (preferably point form) - Judicious inclusion of information about how stressful a cancer diagnosis is
Relevance of booklets not readily apparent	<ul style="list-style-type: none"> - Tailor to make it more relevant to patients and partners (e.g., by cancer type) - Provide an initial workshop or orientation session - Include testimonials
Overwhelmed by amount of information included in the booklets	<ul style="list-style-type: none"> - Series of small booklets - Provide an initial workshop or orientation session - Concise presentation of information (preferably point form) - Consider tailoring based on challenges experienced
Booklets' format unattractive/no hook	<ul style="list-style-type: none"> - Need page turner e.g., cartoons - Use more humor throughout. Use bright colors - Complement with a DVD. Include testimonials
Booklets got lost among all the other resources received	<ul style="list-style-type: none"> - Sell it—make it explicit why someone has to read this resource - Provide an initial workshop or orientation session - Include page turner—cartoons/have an attractive cover - Include a questionnaire at the beginning to identify pertinent booklets - Use existing infrastructure to disseminate the resource (e.g., support groups)
Booklets too depressing or too clinical	<ul style="list-style-type: none"> - Include cartoons/pictures or vignettes - Need to convey that 'everything is under control'



DECISIONS TO BE MAKE	Decision
What should be done (content)	1. Coping and illness self-management skills training 2. Normalizing experiences
When (timing)	Acute post-diagnosis phase
How much (dose, frequency, duration)	Self-directed, but weekly phone calls to encourage use for 8 weeks
Where	Depends on dyads (mainly participants' homes)
How (mode: app, face to face)	Booklets + DVD + CD + online repository + monthly newsletter + weekly phone calls
Who will provide RX	Self-directed – distributed by nurses and other health care professionals
Who will be participate in RX (target clientele)	Patients with cancer (early-stage) and their caregivers who report some distress

Process of developing **CUES**



Problem	Developmental problems of preterm infants: Mother's anxiety & poor sensitivity in interactions with infants predict poor development
Approach(es) to intervention development	Empirical & clinical knowledge <ul style="list-style-type: none"> • Evidence from dissertation & longitudinal studies identify targets of ANX & SEN as influencing development of preterm infants • Evidence on effective Rx (CBT for anxiety & SEN teaching & coaching from RCTs other populations) & I put together these 2 components • Decisions: timing, dose, frequency, methods based on evidence & clinical knowledge (Feeley et al., 2011 re evidence base) • Later meta-analysis of SEN what RX effective, dose (5- 7), methods (video) Lucky choices!
Methods used	Pre-test 3 mothers did program & provided feedback Manual written with content each session, methods & principles
Challenges in process of development	How to provide content for two components of RX in reasonable # sessions during critical care hospitalization
Solutions	Strike balance between amount RX to achieve the desired effects & burden – importance acceptability to moms in pre-test
Lessons learned	Pre-test very valuable, these women provided letters to support grant Training program for interveners developed too with teaching-learning materials

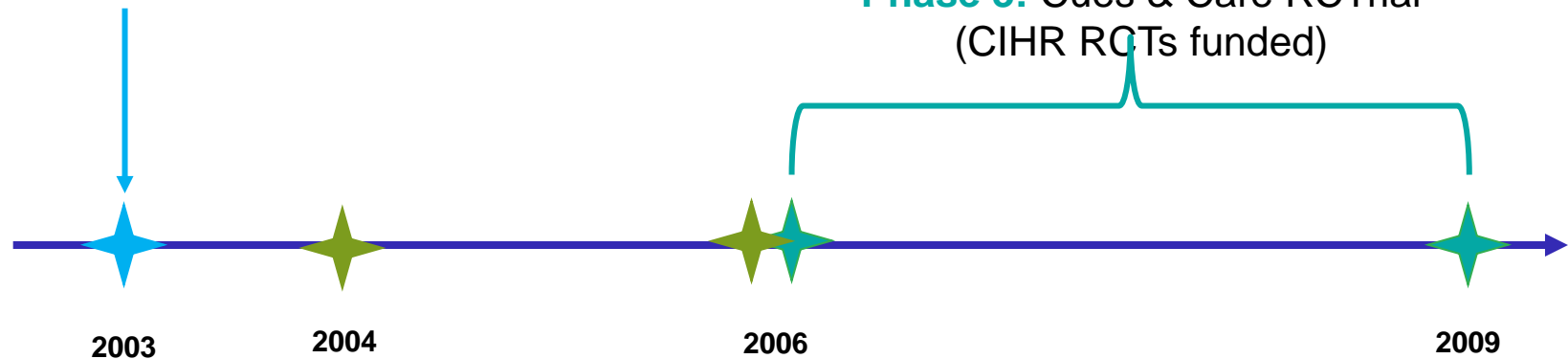
CUES program

DECISIONS	Decision
What should be done (content)	<ol style="list-style-type: none">1. Anxiety management2. Learn to interact sensitivity
When (timing)	During NICU + after to manage transition home
How much (dose, frequency, duration)	4 sessions NICU + 5 th feeding + 6 th after home
Where	5 NICU + 1 home after discharge
How (mode: app, face to face)	Variety: face to face, brochures, DVD, video-feedback
Who will provide RX	Trained nurse interveners or psychologist
Who will participate in RX (target clientele)	Mothers only (feasibility)

Cues program development and assessment of efficacy

Time line (6 years)

Phase 1: Intervention of development

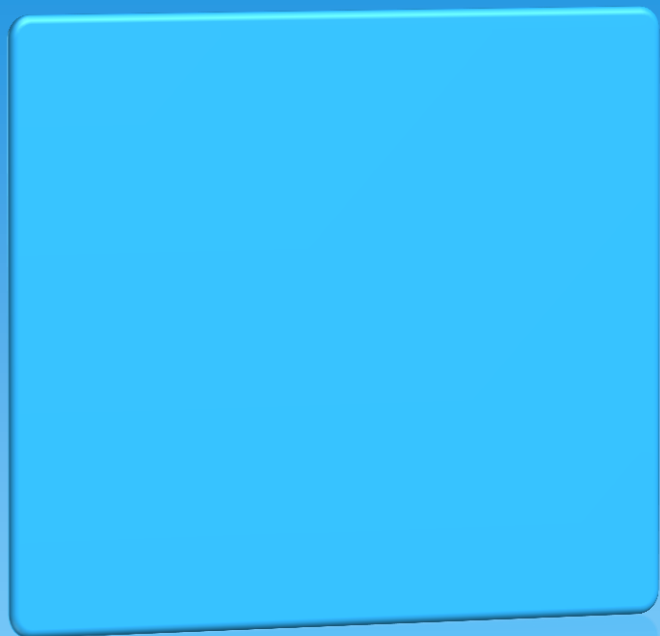


Phase 2: Cues pilot
(RRISIQ funded)



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Medical Research Council (MRC) framework for design and evaluation of complex interventions

Stepwise approach

- Phase 0: Preclinical or theoretical (why should this work?)
- Phase 1: Modelling (how does it work? Developing it)
- Phase 2: Exploratory or pilot trial (optimizing trial measures)
- Phase 3: Definitive randomized controlled trial
- Phase 4: Implementation

Abraham et al., 2015 *in Complex Interventions*

Based on **intervention mapping of Bartholomew (J Cote)**

- Six stages of intervention development:
 1. Needs assessment
 2. Set objectives (primary, secondary)/outcomes
 3. Identify change mechanisms
 4. Determine methods provision (brochures, face to face)
 5. Determine implementation (who, how)
 6. Determine evaluation (what questions should answer in evaluation)

Patient engagement in research (Domecq et al., 2014)

Results:

- No comparative analytic studies to recommend a particular method
- **Benefits of patient engagement:**
 - increased enrollment
 - securing funding
 - Help design study & choosing relevant outcomes
- **Most commonly cited challenges:**
 - Logistics (extra time & funding)
 - Worry of tokenistic engagement
 - “scope creep”: worry irrelevant community concerns and issues
- **Potential solutions include:**
 - Spending adequate time to rebuild reciprocal relationships
 - Fostering mutual respect
 - Developing clear expectations that are explicitly described & documented in protocols