

Complex Health Interventions Dimensions and Challenges in Nursing

January 28th, 2021

Hosted by the Phi Xi Chapter & Nursing School of Coimbra, Portugal.

Presenters



Filipa Ventura
PhD, RN
Junior Researcher
UICISA:E, ESEnfC
Coimbra, Portugal



Margarita Corry
PhD, RGN, RNT
Assistant Professor,
School of Nursing & Midwifery,
Trinity College Dublin
Dublin, Ireland



Odete Araújo
PhD, RN
Assistant Professor,
School of Nursing,
University of Minho
Braga, Portugal

Program

- Concepts, key dimensions
- Medical Research Council framework: past & present
- Complex Interventions in Nursing
- Lessons learned & Reflections
- Take-home messages
- Q&A

Complex Health Interventions

Activities that contain a number of component parts with the potential for interactions between them which, when applied to the intended target population, produce a range of possible and variable outcomes.

Richards & Hallberg, 2015

Simple *versus* Complex



Simplicity

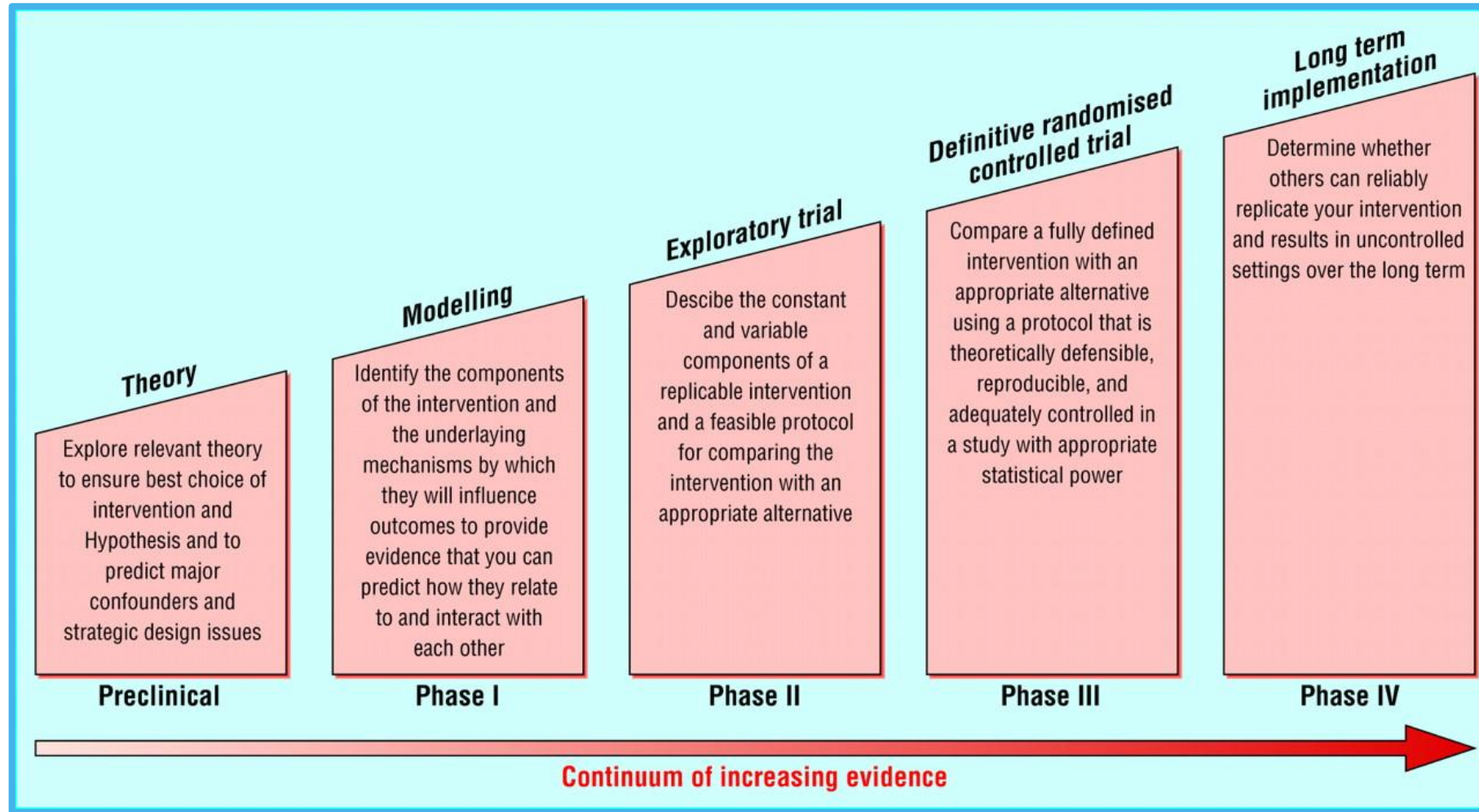
Complexity

In the health domain, very few interventions will be truly simple the number of components and range of effects might vary and as such we might argue that there is a continuum of simplicity-complexity depending on each of these complexity dimensions.

Oral antibiotic agent prescribed by a doctor and taken by a patient in order to reduce an infection

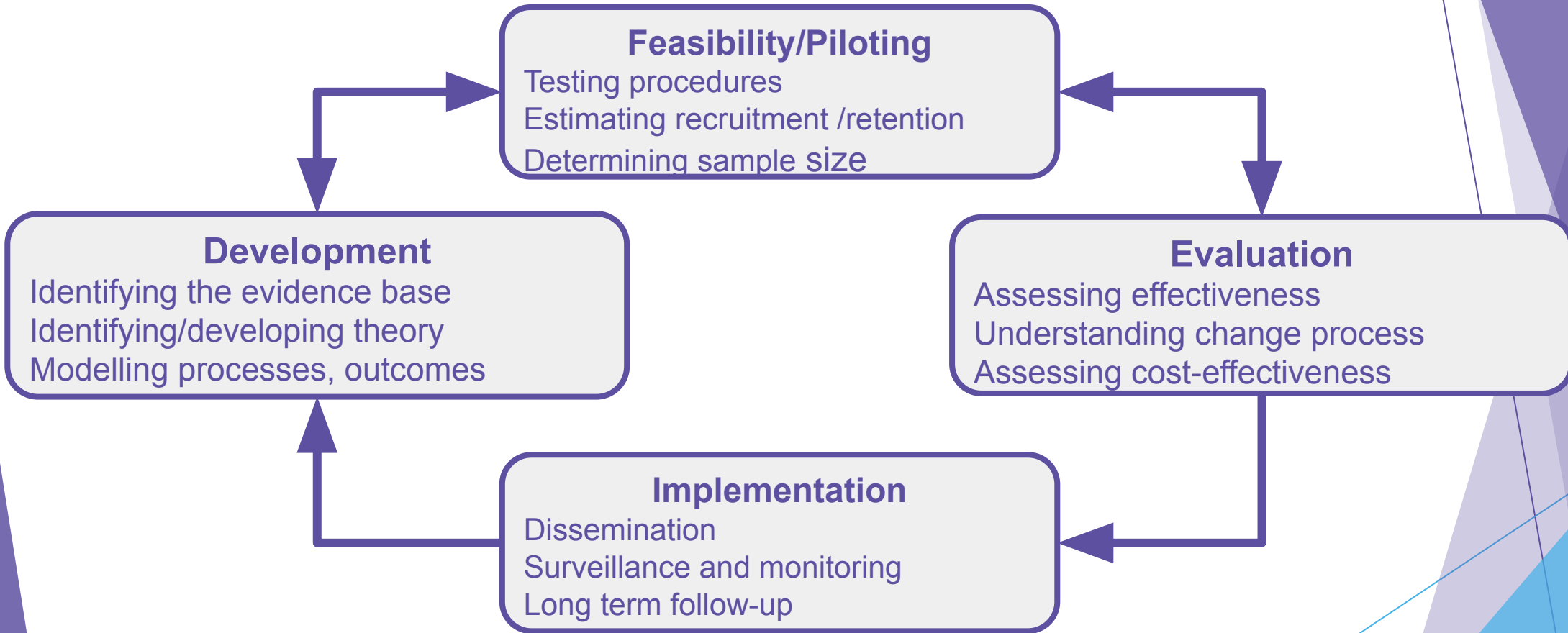
Richards & Hallberg, 2015

Historical perspective



Campbell et al., 2000

MRC framework for complex health interventions



Craig et al., 2008

New guidance key dimensions

Despite the apparent segmentation in phases, the research process follows a circular process where each feedback loop between both previous and subsequent activities in each phase informs continuously the foundations of the intervention in an iterative and reflexive manner. This reflexive process also sets more attention in the early and later phases of the research process, that is, the development and piloting, and the implementation.

Circularity

Systematic reviews

Accounts for the importance of systematic reviews in both planning and reporting complex interventions: The research process is initiated with RQs that are important to patients and practitioners but the new research has to build on a systematic and comprehensive understanding of what is already known, and if these questions can be answered at a reasonable cost. So this new guidance endorses the importance of systematic reviews, not only at the early-stages of intervention development but even later in the other phases.

There is a strong recognition of the context as a complexity dimension where the intervention will roll out:

- other evaluation designs rather than RCTs have emerged like the pragmatic trials.
- and it reinforces the need to plan for implementation from the early beginning of intervention development rather than approaching these issues as a final step

The context

Patient & Public involvement

Endorses Patient & Public involvement at all stages of the research process:

- involvement of end-users (patients, residents... service users) and stakeholders, if we want interventions to be usable, used and useful

MRC framework ... to nowadays

Google Scholar "medical research council framework"

Articles 9 results (0.14 sec)

Any time
Since 2021
Since 2020
Since 2017
Custom range

— 2000

Search

Google Scholar "medical research council framework"

Articles About 116 results (0.04 sec)

Any time
Since 2021
Since 2020
Since 2017
Custom range

2000 — 2008

Search

Google Scholar "medical research council framework"

Articles About 1,630 results (0.03 sec)

Any time
Since 2021
Since 2020
Since 2017
Custom range

2008 — 2021

Search

Realist complex intervention science: applying realist principles across all phases of the **Medical Research Council framework for developing and evaluating complex ...**

A Fletcher, F Jamal, G Moore, RE Evans... - ..., 2016 - journals.sagepub.com

The integration of realist evaluation principles within randomised controlled trials ('realist RCTs') enables evaluations of complex interventions to answer questions about what works, for whom and under what circumstances. This allows evaluators to better develop and refine ...

☆ Cited by 136 Related articles All 8 versions

Utilization of the medical research council evaluation framework in the

Importance for Nursing

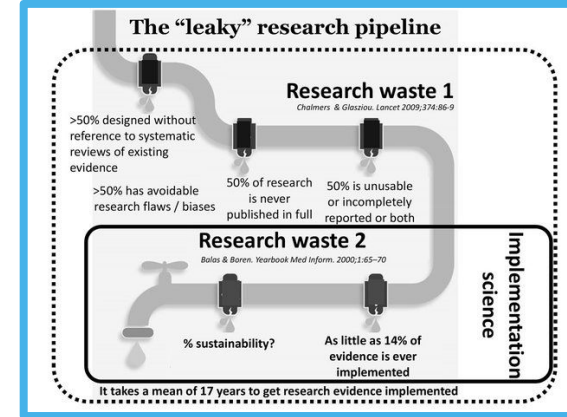


It is not only about effectiveness, for nurses is almost even more important to know and understand how the intervention works, to whom?

If the main goal is to reach person-centred care.

Nursing is complex in its essence:

- 1) wide-range of activities and our scope of action is becoming even greater as organizational changes lead to shorter hospital stays and greater individual responsibility to self-care
- 2) these activities are highly complex
- 3) roll out in multiple care environments



We need to reduce the research waste:
We need methodological rigour and processes that take us beyond:

- a) descriptive research into experimental,
- b) cross-sectional designs to longitudinal,
- c) from context-specific results to generalisable results
- d) from introspective research into implementation processes.

Hallberg, 2009

De Geest et al., 2020

Guidelines and frameworks for developing and testing nursing interventions

Conn et al., 2001
Whittemore and Grey, 2002
Van Meijel et al., 2004
Corry et al., 2013

“The goal of nursing intervention research is to develop effective interventions that are important to practice, feasible, acceptable to patients and practitioners, and easily disseminated into current models of care”

Whittemore and Grey, 2002, p. 119

Approaches

- ▶ Overview of the issues that need to be considered in the design of interventions (Conn et al. 2001)
- ▶ Phases (Whittemore and Grey, 2002; Campbell et al. 2007; Craig et al. 2008)
- ▶ Stages or building blocks (Van Meijel et al. 2004)
- ▶ Model for developing nursing interventions (Corry *et al.* 2013)

Table 1. Considerations in Designing Interventions

Attribute	Strategies to Enhance Interventions
Conceptual basis	<ol style="list-style-type: none"> 1. Explicit conceptual framework entirely consistent with phenomenon 2. Intervention mechanisms can be explained by conceptual framework 3. Conceptual framework explains central constructs amenable to intervention 4. Specific interventions (including timing) are suggested by conceptual framework
Previous descriptive research	<ol style="list-style-type: none"> 1. Intervention based on constructs accounting for large amounts of variance 2. Intervention based on constructs consistently predicting outcome variables across diverse study methods
Related intervention literature	<ol style="list-style-type: none"> 1. Intervention dose similar to documented effective intervention doses 2. Attributes of effective interventions included in experimental intervention 3. Intervention based on published, unpublished, and meta-analytic reports about similar interventions
Intervention targeted for population	<ol style="list-style-type: none"> 1. Intervention designed for the specific population 2. Differential assignment by subject attributes 3. Setting based on conceptual framework and phenomenon
Specificity/generality	<ol style="list-style-type: none"> 1. Level of specificity/generality consistent with the conceptual framework 2. Level of specificity/generality congruent with the phenomenon
Single/bundled interventions	<ol style="list-style-type: none"> 1. Bundling intervention decisions based on conceptual framework 2. Rationale provided for each component of a bundled intervention
Intervention delivery	<ol style="list-style-type: none"> 1. Interventionist qualified to deliver the intervention 2. Interventionist characteristics appropriate for the specific population 3. Subject compliance ensured/addressed if subject behavior affects outcome 4. Intervention burden on participants minimized 5. Intervention delivery mode based on conceptual framework/empirical literature 6. Intervention setting and timing considered integral components of the intervention
Dose	<ol style="list-style-type: none"> 1. Session/treatment duration consistent with conceptual framework 2. Frequency of treatments based on empirical literature 3. Duration of treatments over time adequate to affect outcome

Whittemore and Grey (2002)

Places emphasis on the importance of synthesis of clinical, scientific and participant perspectives.

Argues that health services research, methodological research and descriptive research are all important for intervention development.

Whittemore and Grey (2002)

Nursing Interventions

Table 1. National Institutes of Health Phases of Clinical Trials

Phase	Purpose
I	To test a new biomedical or behavioral intervention in a small group for the first time to establish safety.
II	To study the biomedical or behavioral intervention in a larger group of people to determine efficacy and to further evaluate safety.
III	To study the efficacy of the biomedical or behavioral intervention in large groups by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects.
IV	To monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread usage.

Whittemore and Grey, 2002, p. 116

Whittemore and Grey (2002)

Table 2. Phases of Nursing Clinical Trials

Phase	Outcome
I – Basic research Concept and theory development Exploratory and descriptive research Synthesis of research Methodological research Health services research Intervention development research	Establish the content, strength, and timing of intervention. Establish outcome measures.
II – Pilot research Analysis of adequacy of theoretical framework and endpoints Analysis of implementation of intervention Establish protocol Preliminary analysis of efficacy (effect size) Preliminary analysis of extraneous factors	Refine intervention and outcome measures.
III – Efficacy clinical trial Analysis of intervention effect in ideal setting Emphasis of study on high internal validity Determination of mediators and moderators to intervention Preliminary cost analysis	Determine clinical efficacy.
IV – Effectiveness clinical trials Analysis of intervention effect in clinical practice Emphasis of study on high external validity Determination of clinical utility Cost analysis Comparative and longitudinal designs	Determine clinical effectiveness.
V – Effects on public health Wide-scale implementation	Determine effects on public health.

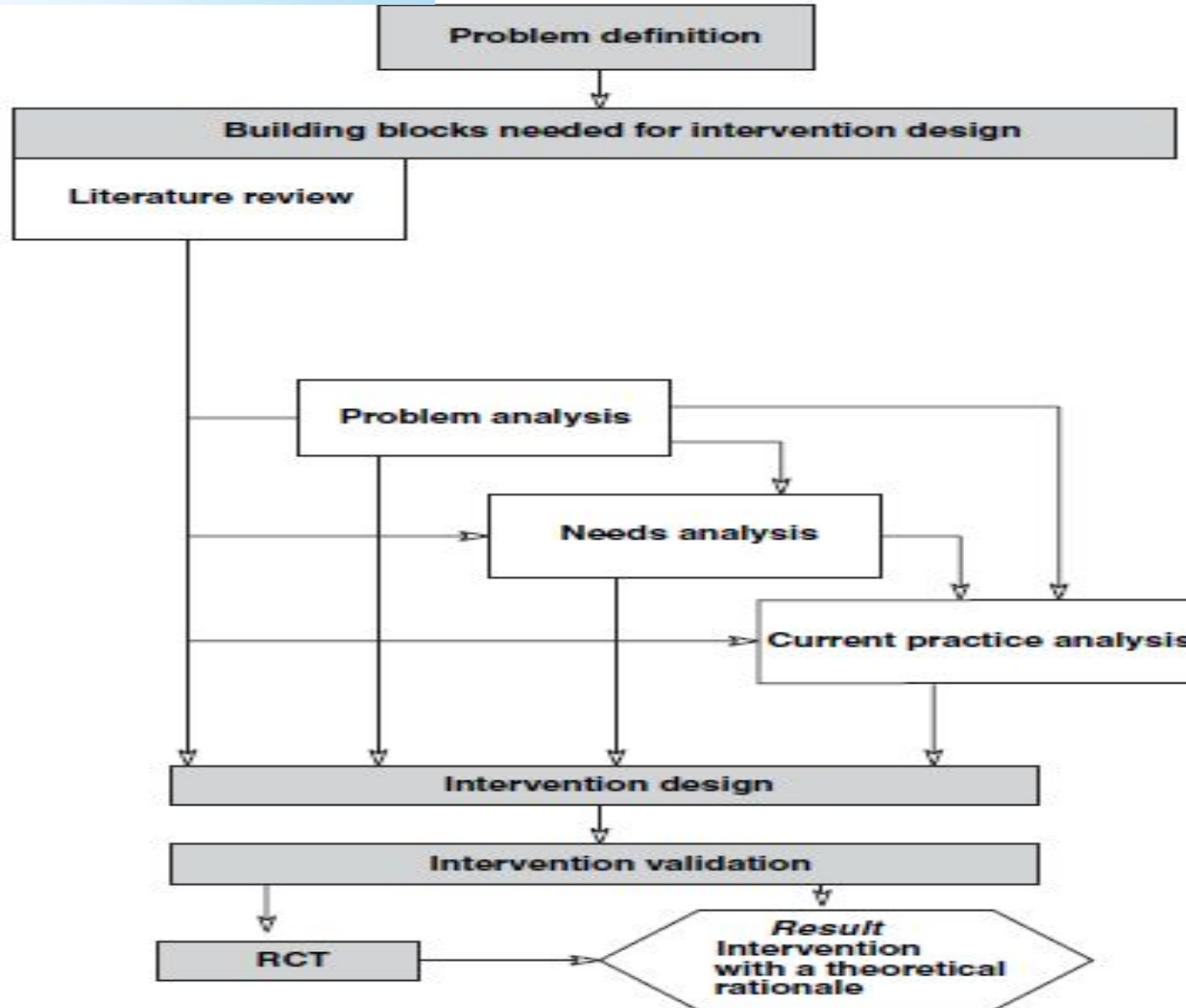


Figure 1 Diagram of developing evidence-based interventions.

Corry et al. 2013

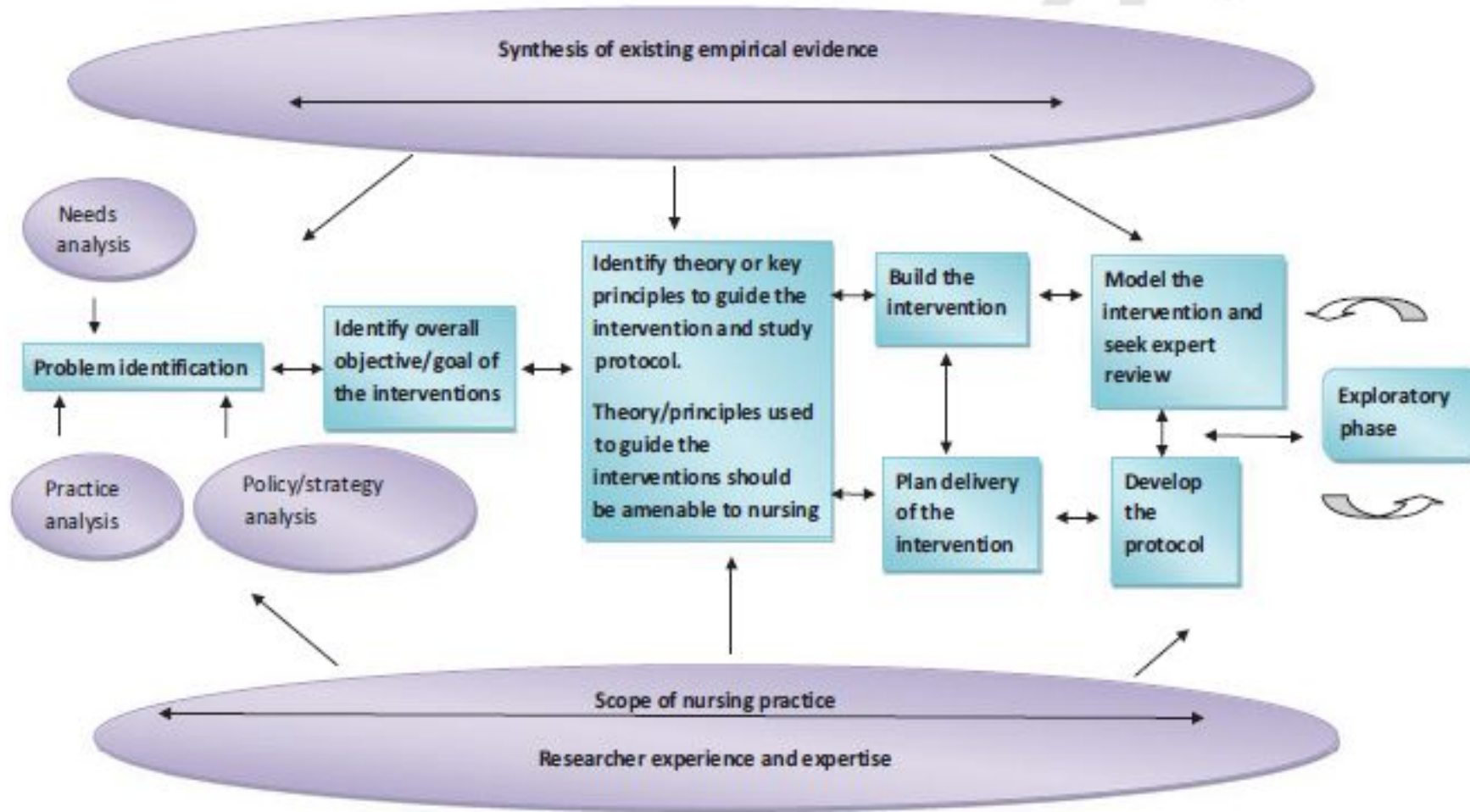
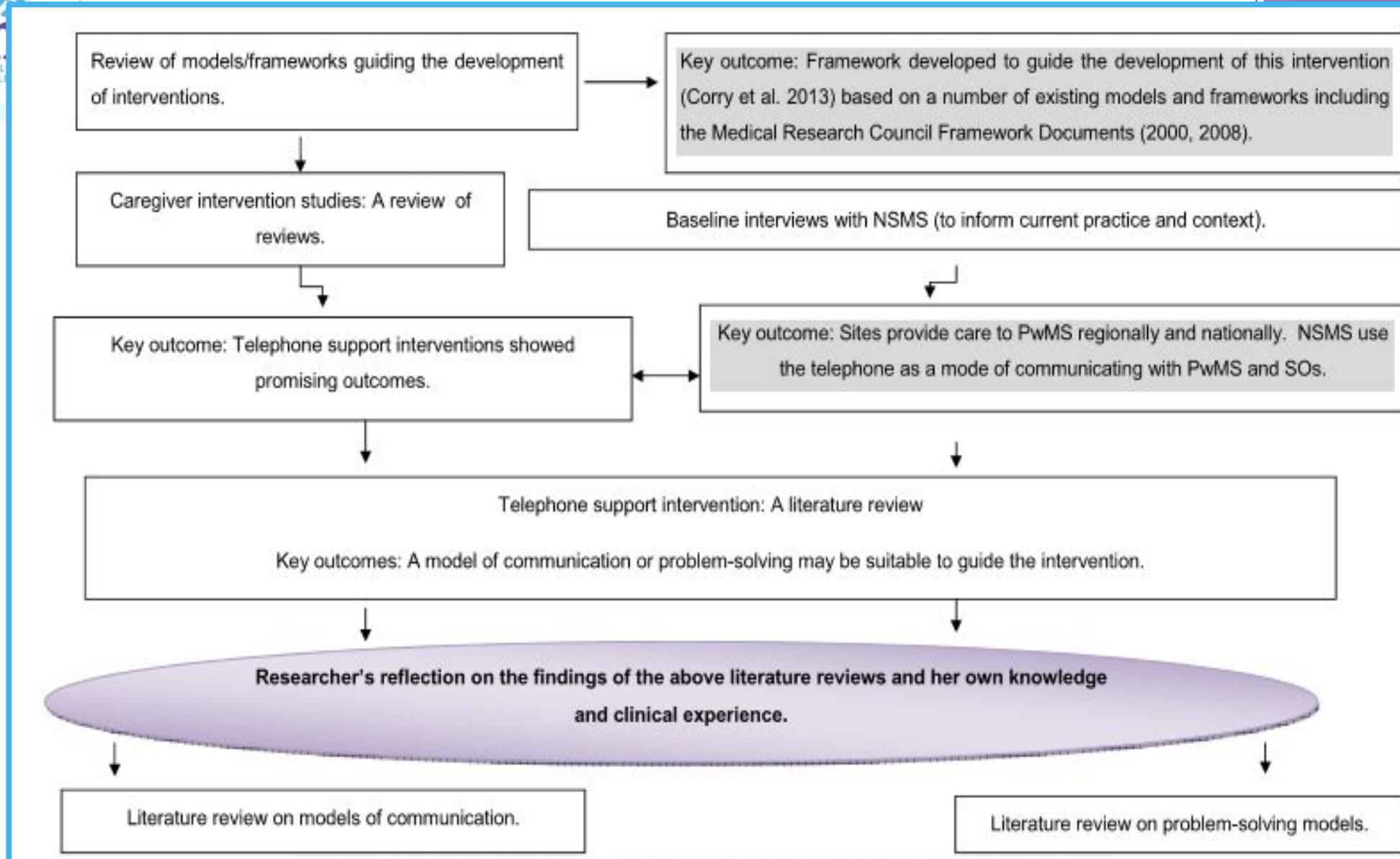


Figure 2 Model for developing complex interventions in nursing.



Diagrammatic representation of the approach to theory identification (Corry 2015)

CLINICAL SCHOLARSHIP

Content Validity and Satisfaction With a Stroke Caregiver Intervention Program

Tamilyn Bakas, RN, DNS, FAHA, FAAN¹, Carol J. Farran, RN, DNSc, FAAN², Joan K. Austin, RN, DNS, FAAN³, Barbara A. Given, RN, PhD, FAAN⁴, Elizabeth A. Johnson, RN, PhD⁵, & Linda S. Williams, MD, FAHA, FAAN⁶

1 Alpha, Professor, Indiana University School of Nursing, Indianapolis, IN

2 Gamma Phi, Professor and the Nurses Alumni Association Chair in Health and the Aging Process, Rush University College of Nursing, Chicago, IL

3 Alpha, Distinguished Professor Emeritus, Indiana University School of Nursing, Indianapolis, IN

4 Alpha Psi, University Distinguished Professor, Michigan State University College of Nursing, East Lansing, MI

5 Alpha, Assistant Professor, Ball State University School of Nursing, Muncie, IN

6 Chief of Neurology, Richard L. Roudebush Veterans Administration Medical Center, Associate Professor, Indiana University School of Medicine, Indianapolis, IN

Key words

Stroke, family caregivers, intervention studies, needs assessment, feasibility, satisfaction, validity

Correspondence

Dr. Tamilyn Bakas, Indiana University School of Nursing, 1111 Middle Drive, NU 417, Indianapolis, IN 46202. E-mail: tbakas@iupui.edu

Accepted: May 22, 2009.

doi: 10.1111/j.1547-5069.2009.01282.x

Abstract

Background and Purpose: Establishing evidence of content validity and satisfaction is an integral part of intervention research. The purpose of this article is to describe content validity and satisfaction relative to the Telephone Assessment and Skill-Building Kit (TASK), an 8-week follow-up program based on individualized assessment of stroke caregiver needs.

Design and Methods: The TASK intervention enables caregivers to develop skills based on assessment of their own needs. During the development of the TASK program, 10 experts rated the validity of the TASK intervention components for accuracy, feasibility, acceptability, and problem relevance. After incorporating feedback from the experts, a randomized controlled clinical trial was instituted using a convenience sample of 40 stroke caregivers to determine satisfaction (usefulness, ease of use, and acceptability) with the TASK intervention ($n=21$) compared with an attention control group ($n=19$). Data collection occurred between March 2005 and June 2006. Data were analyzed using descriptive statistics, independent sample *t* tests, and content analysis.

Findings: Expert ratings on a 1 to 5 scale, with 5 being strongly agree, provided evidence of content validity (accuracy 4.71, feasibility 4.46, acceptability 4.40, problem relevance 4.67). Caregivers in the TASK group scored significantly higher than the attention control group on all satisfaction measures (usefulness $p=.02$; ease of use $p=.02$; acceptability $p=.05$). Qualitative comments from caregivers provided further evidence of satisfaction.

Conclusions: Evidence of content validity and user satisfaction for the TASK intervention relative to an attention control group was found.

Clinical Relevance: The TASK program may be a viable telephone-based program that can be implemented by nurses to support family caregivers during the first few months after stroke survivors are discharged home.

Open Journal of Nursing, 2016, 6, 303-308

Published Online April 2016 in SciRes. <http://www.scirp.org/journal/ojn>

<http://dx.doi.org/10.4236/ojn.2016.64031>



Part A: The Development of mI SMART, a Nurse-Led Technology Intervention for Multiple Chronic Conditions

Jennifer A. Mallow^{1*}, Laurie A. Theeke¹, Rebecca Walls², Elliott Theeke¹, Brian K. Mallow³

¹School of Nursing, West Virginia University, Morgantown, West Virginia, USA

²Milan Puskar Health Right, Morgantown, West Virginia, USA

³Sovern Run, LLC, Albright, West Virginia, USA

Email: jamallow@hsc.wvu.edu, ltheeke@hsc.wvu.edu, etheeke@hsc.wvu.edu, bkmallow@gmail.com

Received 29 March 2016; accepted 25 April 2016; published 28 April 2016

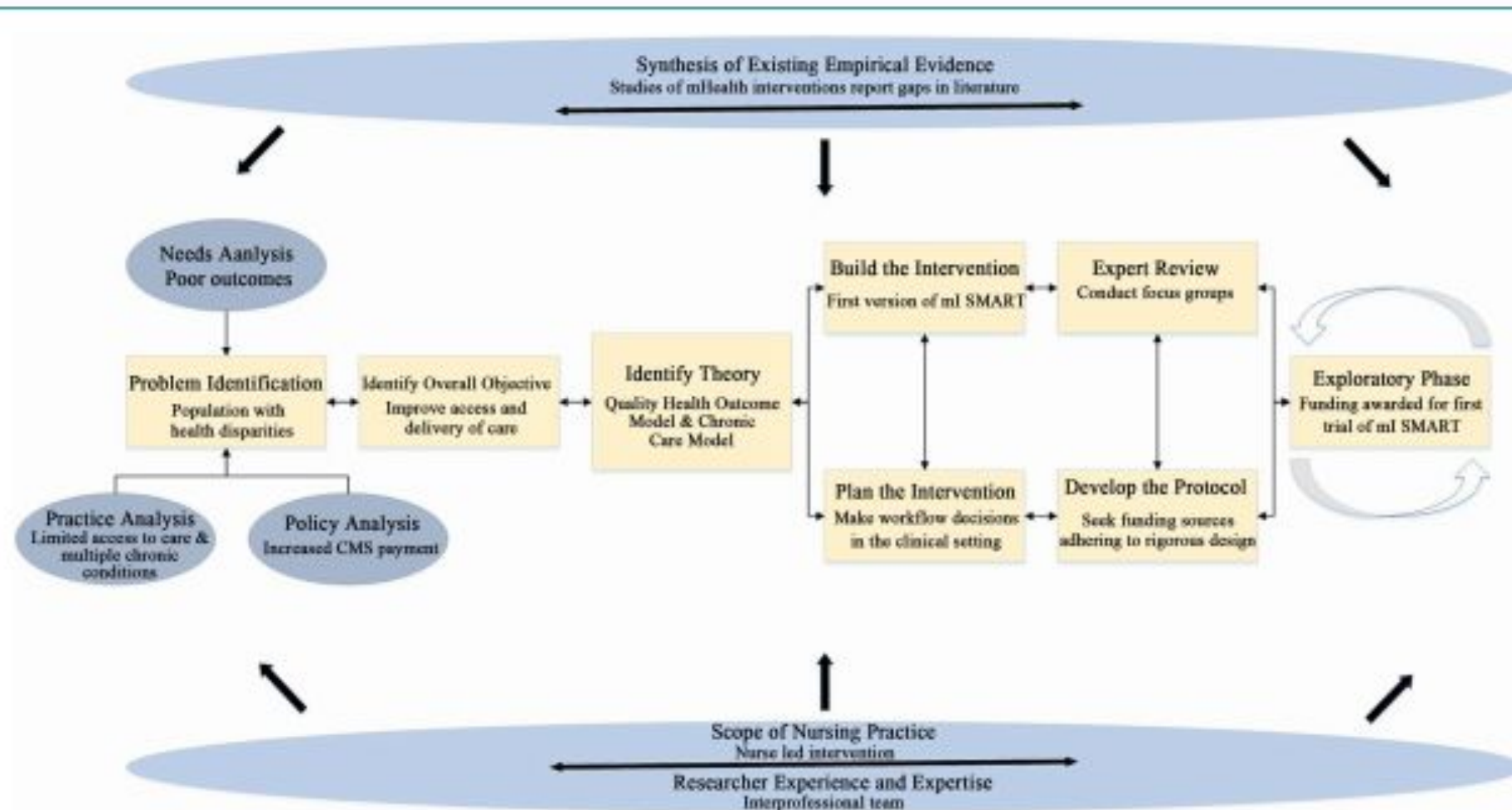


Figure 1. Operationalization of the model for developing complex interventions in nursing. This figure is based on the model found in [15].

shift in the traditional rural healthcare delivery paradigm to one that uses technology is expected to result. The

Part B: The Feasibility and Acceptability of mI SMART, a Nurse-Led Technology Intervention for Multiple Chronic Conditions

Jennifer A. Mallow^{1*}, Laurie A. Theeke¹, Rebecca Walls², Elliott Theeke¹, Brian K. Mallow³

¹School of Nursing, West Virginia University, Morgantown, West Virginia, USA

²Milan Puskar Health Right, Morgantown, West Virginia, USA

³Sovern Run, LLC, Albright, West Virginia, USA

Email: jamallow@hsc.wvu.edu, ltheeke@hsc.wvu.edu, etheeke@hsc.wvu.edu, bkmallow@gmail.com

Received 29 March 2016; accepted 25 April 2016; published 28 April 2016

Copyright © 2016 by authors and Scientific Research Publishing Inc.

This work is licensed under the Creative Commons Attribution International License (CC BY).

<http://creativecommons.org/licenses/by/4.0/>



Open Access

Abstract

Background: An opportunity to improve care of multiple chronic conditions for those living in rural areas of the country may exist through the use of technology. Integrating technology interventions into existing rural health systems allows for increased access to healthcare services and augments self-management ability for patients. However, questions remain about acceptability and feasibility of technology use in rural populations. The purpose of this paper is to present the feasibility of mI-SMART, a HIPAA compliant, web-based, structure of mHealth sensors and mobile devices designed to overcome the known health determinant of access to care for rural, chronically ill patients by using technology. **Methods:** The study was conducted at a primary-care clinic that provided healthcare at no or low cost to low income adults. Inclusion criteria encompassed adults, with at least one chronic condition, having at least 3rd grade reading level, without having dementia/psychosis. Each participant was given a Nexus7 tablet and Bluetooth self-monitoring

HOSTED BY



Contents lists available at ScienceDirect

International Journal of Nursing Sciences

journal homepage: <http://www.elsevier.com/journals/international-journal-of-nursing-sciences/2352-0132>



Special Issue: Advanced Practice Nursing

The effectiveness of mI SMART: A nurse practitioner led technology intervention for multiple chronic conditions in primary care



Jennifer A. Mallow^{a,*}, Laurie A. Theeke^a, Elliott Theeke^a, Brian K. Mallow^b

^a West Virginia University, School of Nursing, United States of America

^b Sovern Run, LLC, United States of America

ARTICLE INFO

Article history:

Received 31 October 2017

Received in revised form

14 March 2018

Accepted 27 March 2018

Available online 31 March 2018

Keywords:

Health disparities

mHealth

Multiple chronic conditions

Nursing informatics

ABSTRACT

Aims: Used as integrated tools, technology may improve access and outcomes of care. A new intervention that integrates multiple technologies called mI SMART has been developed, implemented, and evaluated by Nurse Practitioners. The aim of this paper is to present the initial effectiveness of a web-based, structure of sensors and mobile devices designed to overcome the known health determinant of access to care for rural, chronically ill patients by using technology.

Methods: The study was conducted at a community primary-care clinic that provides free healthcare to impoverished adults. Adults with at least one chronic condition, a minimum of 3rd grade reading level, and without dementia/psychosis were recruited. Participants were given a Nexus7 tablet and Bluetooth self-monitoring devices. The intervention lasted for 12 weeks. Blood glucose, blood pressure, and weight were collected using the provided Bluetooth devices and means were evaluated with paired-samples t-tests before and after the intervention.

Davis et al. *BMC Nursing* (2020) 19:9
<https://doi.org/10.1186/s12912-020-0400-9>

BMC Nursing

RESEARCH ARTICLE

Open Access

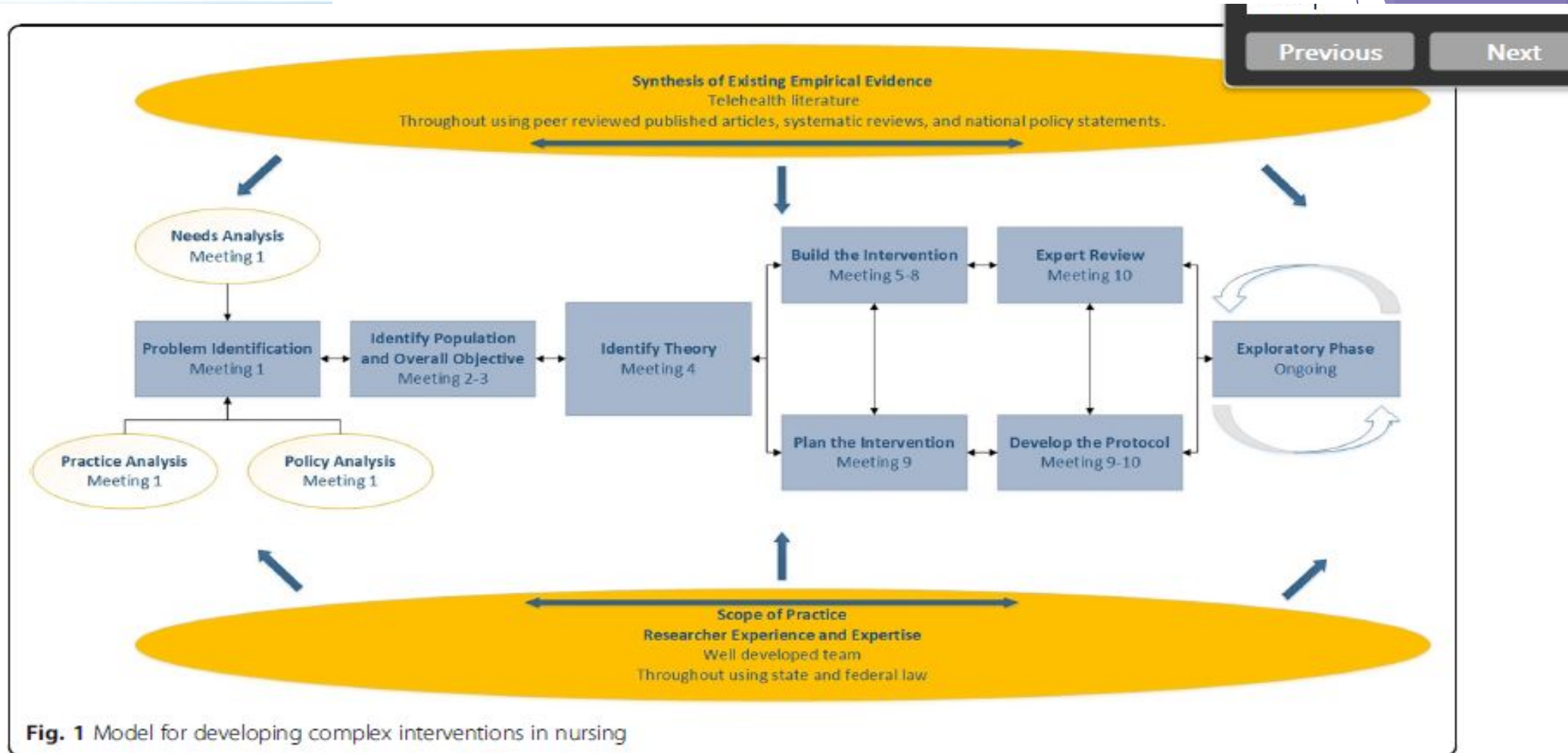
Designing a multifaceted telehealth intervention for a rural population using a model for developing complex interventions in nursing



Stephen M. Davis^{1,2*} , Amanda Jones¹, Margaret E. Jaynes³, Kori N. Woodrum¹, Marcus Canaday⁴, Lindsay Allen¹ and Jennifer A. Mallow⁵

Abstract

Background: Telehealth interventions offer an evidenced-based approach to providing cost-effective care, education, and timely communication at a distance. Yet, despite its widespread use, telehealth has not reached full potential.

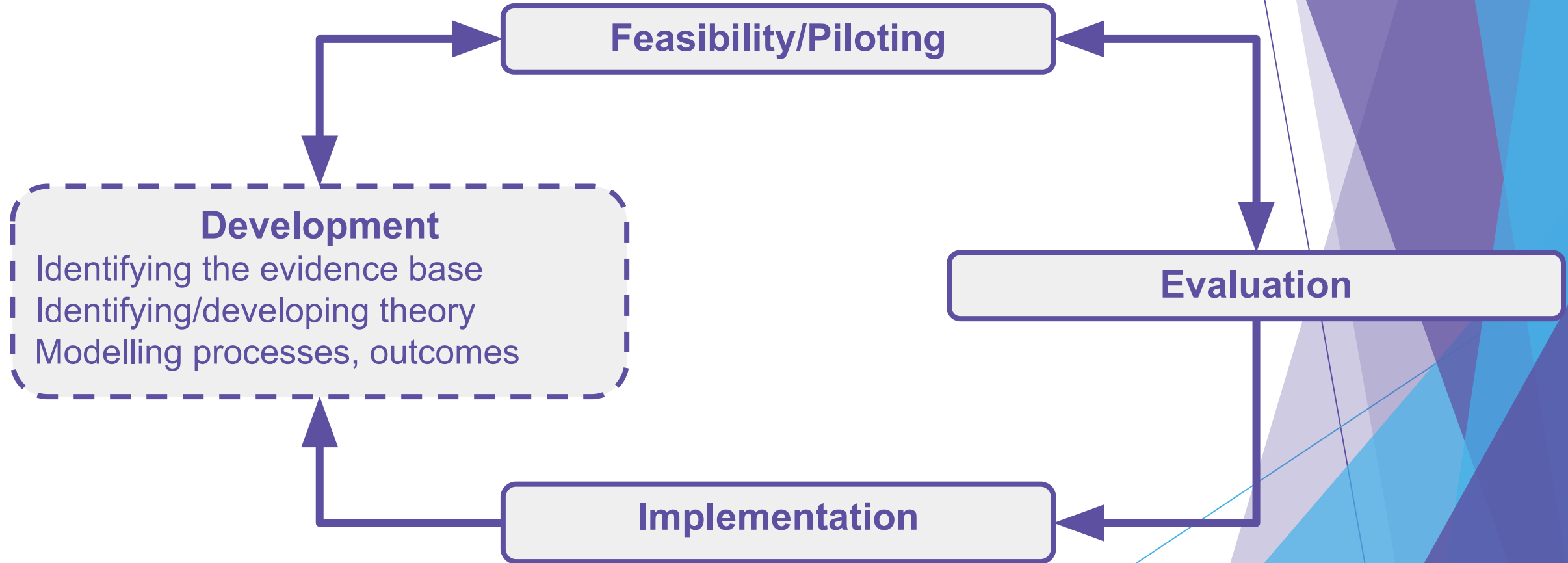


Davis et al. 2020, p. 3 of 9

Outline

- Complex interventions design (MRC, 2008) adapted to empowerment of informal caregivers of older people after a stroke.
- Phase 1 - Development
- Phase 2 - Feasibility and Piloting
- Phase 3 - Evaluation
- Reflections

Phase I: Complex Intervention Design



Identifying the evidence base

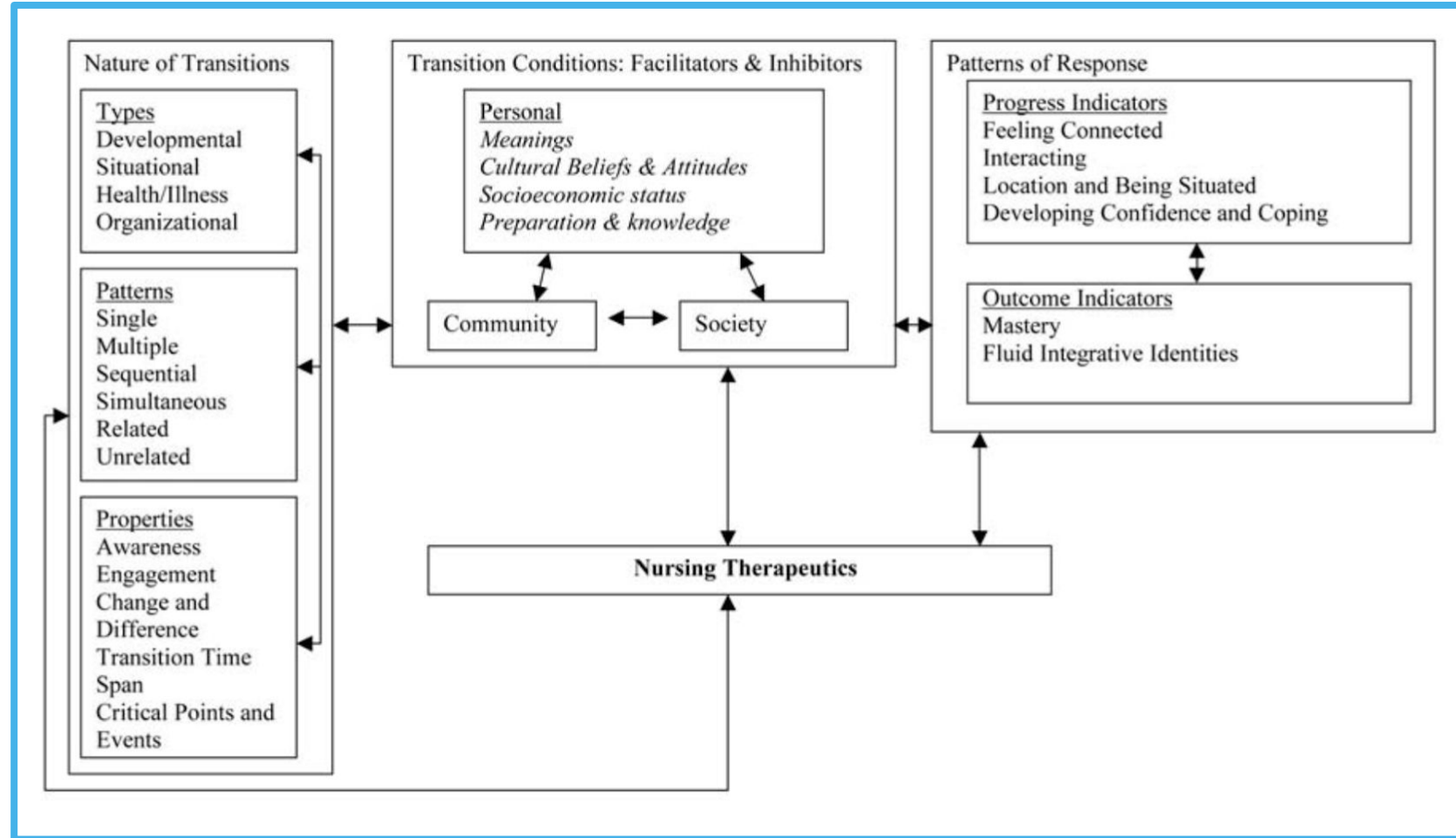
► **The evidence has shown:**

- Stroke remains a complex health problem in the 21st century (incidence rates of 1 65 per 1000 population for first-ever strokes).
- After hospitalization admission, up to 80% of patients are discharged home and many will be dependent on informal caregivers, usually family members, to provide assistance on self-care (including bathing, dressing and other basic activities of selfcare).
- For some people, caregivers avoid or delay hospitalization and institutionalization. (Shyu, *et al.*, 2010; Truelsen, *et al.*, 2006; Larson, *et al.*, 2005)

► **However, many informal caregivers have reported:**

- Dissatisfaction with quantity and quality of the information received after hospital discharge.
- Lack of Preparedness and of Empowerment to take care / “put hands on”.
- High levels of anxiety, fear, poor health status and emotional problems. (Legg *et al.*, 2012; Hafsteinsdóttir *et al.*, 2011; Marsden *et al.*, 2010; Kalra *et al.*, 2004; Smith *et al.*, 2004)

Identifying theory



Transitions: a middle-range theory (Meleis, 2010)

Design

Randomized Trial (single-blinded)/randomization (1:1)

Setting

Community Health Units from Northern Portugal (ACES Cávado I Braga, II Gerês/Cabreira & III Barcelos/Esposende)

Study population/inclusion criteria

Inclusion criteria: (1) they provide care to an old stroke survivor (over 65 years of age); (2) they do not have a cognitive impairment; (3) they must live in the Cavado Region covered by ACES I, II and III; (4) they should give the informed consent. In addition, older stroke survivors will be eligible to enter in this study if they: (1) have become dependent for daily activities; (2) should give the informed consent

Intervention

Informal caregivers of older stroke survivors who integrated the InCARE project received an intervention programme to develop handling techniques regarding mobility, bathing, (un)dressing, transferring, positioning, eating and drinking, using technical devices after 1 week (session 1), 1 month (session 2) and 3 months (session 3) after hospital discharge; they were also encouraged to use telephone support on the 3rd, 6th, 8th and 10th weeks post discharge.

This aimed at facilitating the caregiver's adjustment to stroke demands by increasing his/her knowledge and practical skills to support his/her decision-making.


Outcomes

Outcome and instrument	Caregivers vs. Older people stroke survivors	Data collection time		
		T0 (1 week)	T1 (1 month)	T2 (3 months)
Primary outcomes				
Escala de Capacidades do Prestador Informal de Cuidados de Idosos Dependentes por AVC (ECPICID-AVC)	Informal caregivers	X	X	X
Secondary outcomes				
Questionário de Avaliação da Sobrecarga para Cuidadores Informais (QASCI)	Informal caregivers		X	X
Health Quality of Life (Qol) – Short Form-36 (SF-36)	Informal caregivers		X	X
Physical functioning (Barthel Index)	Older people stroke survivors		X	X
Hospitalization (yes/no)	Older people stroke survivors		X	X
Institutionalization (yes/no)	Older people stroke survivors		X	X

Outcomes measures and data collection of informal caregivers and older people stroke survivors

Complex Interventions Design

Important!

 The TIDieR (Template for Intervention Description and Replication) Checklist* Information to include when describing an intervention and the location of the information		Where located **	
Item number	Item	Primary paper (page or appendix number)	Other † (details)
1.	BRIEF NAME Provide the name or a phrase that describes the intervention.	_____	_____
2.	WHY Describe any rationale, theory, or goal of the elements essential to the intervention.	_____	_____
3.	WHAT Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	_____	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	_____	_____
5.	WHO PROVIDED For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	_____	_____
6.	HOW Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	_____	_____
7.	WHERE Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	_____	_____

JAN

Informing Practice and Policy Worldwide through Research and Scholarship

PROTOCOL

Intervention in informal caregivers who take care of older people after a stroke (InCARE): study protocol for a randomised trial

Odete Araújo, Isabel Lage, José Cabrita & Laetitia Teixeira

Accepted for publication 22 April 2015

Correspondence to O. Araújo:
e-mail: odete.araujo@ese.uminho.pt

Odete Araújo MSc RN
Assistant Professor, PhD Student
School of Nursing, University of Minho,
Braga, Portugal

Isabel Lage MSc PhD RN
Full Professor
School of Nursing, University of Minho,
Braga, Portugal

José Cabrita PhD
Emeritus Professor
Faculty of Pharmacy, University of Lisbon,
Portugal

Laetitia Teixeira PhD
Researcher
Research and Education Unit on Ageing
(UNIFAI), Institute for the Biomedical
Sciences Abel Salazar, University of Porto,
Portugal

ARAÚJO O., LAGE I., CABRITA J. & TEIXEIRA L. (2015) Intervention in informal caregivers who take care of older people after a stroke (InCARE): study protocol for a randomised trial. *Journal of Advanced Nursing* 71(10), 2435–2443. doi: 10.1111/jan.12697

Abstract

Aim. This study aims at describing an intervention based on informal caregivers' skills when taking care of older people after a stroke (InCARE).

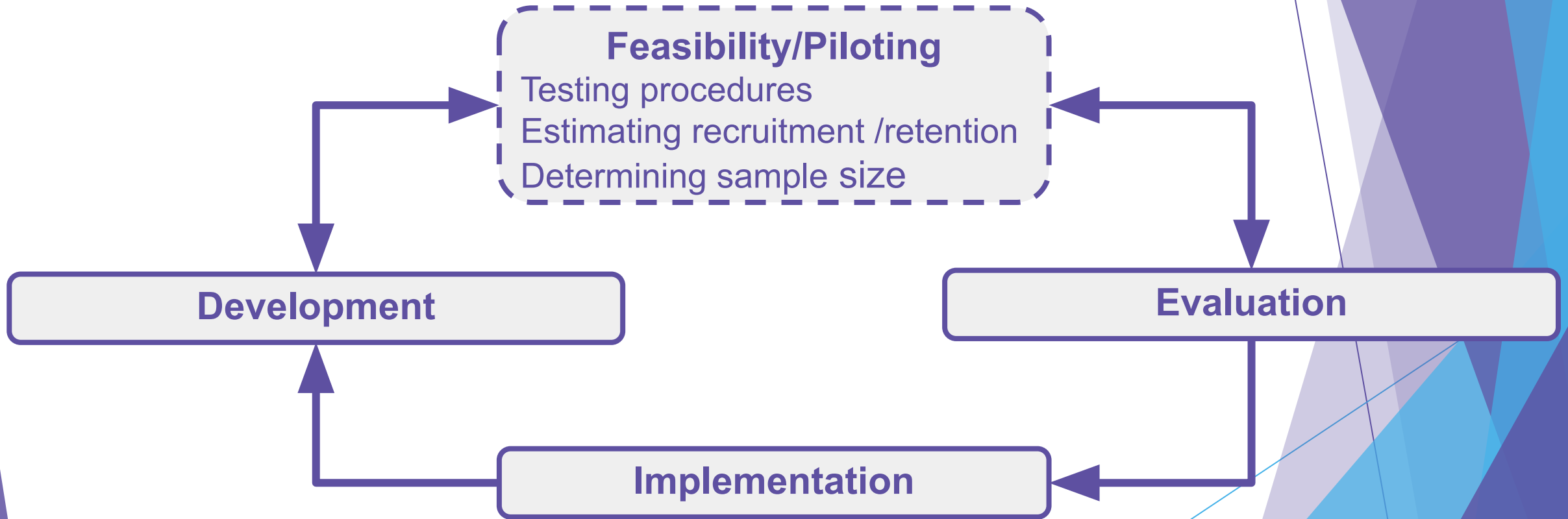
Background. Most informal caregivers feel unprepared to deliver assistance in activities of daily living at home. This lack of preparedness can lead to misconceptions, burden and affect their health, which, consequently, may imply hospital readmissions or early institutionalization of the older adults.

Design. A single blinded randomised trial.

Methods. This study will recruit 198 dyads, comprising old stroke survivors and their caregivers, who will be divided into two groups: intervention and control (protocol approved in May 2013). Inclusion criteria: (informal caregivers) absence of cognitive impairment; resident in the Cávado Region; to return the informed consent (older people) are over 65 years of age; have had a first stroke and; be dependent on at least one of the self-care activities post hospital discharge. Primary outcome: informal caregivers' skills. Secondary outcomes: include burden and Health Quality of Life in informal caregivers; functionality, hospital readmission and institutionalization of older people stroke survivors. measured 1

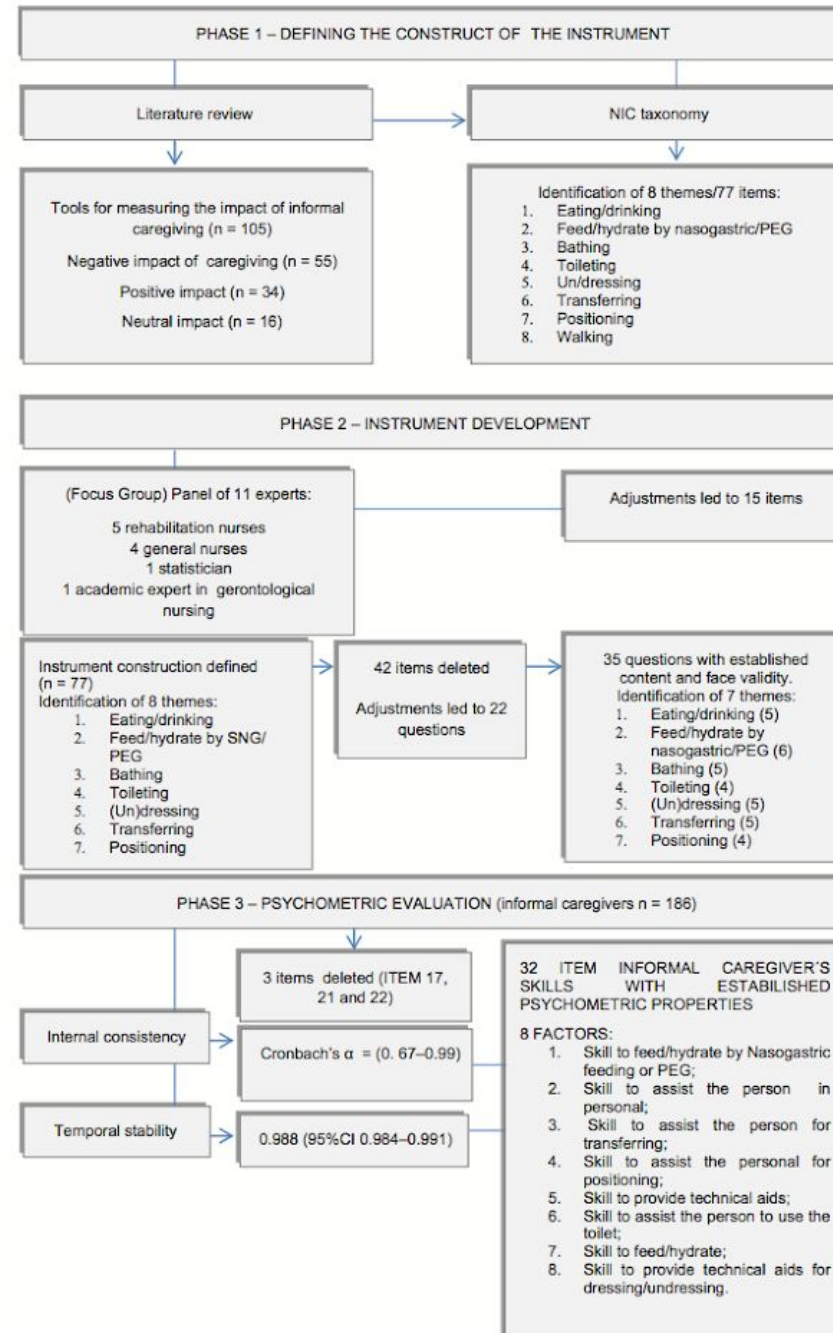
Do not forget Protocol!

Phase II: Feasibility and piloting



Testing Procedures

► Process of instrument development



Development and psychometric properties of ECPCID-AVC to measure informal caregivers' skills when caring for older stroke survivors at home

Odete Araújo PhD Student, MSc, RN (Assistant Professor)¹, **Isabel Lage** PhD, MSc, RN (Full Professor)¹,
José Cabrita PhD (Emeritus Professor)² and **Laetitia Teixeira** PhD (Researcher)³

¹School of Nursing, University of Minho, Braga, Portugal, ²Faculty of Pharmacy, University of Lisbon, Lisbon, Portugal and ³Research and Education Unit on Ageing (UNIFAI), Institute for the Biomedical Sciences Abel Salazar, University of Porto, Porto, Portugal

Scand J Caring Sci; 2016; 30; 821–829

Development and psychometric properties of ECPCID-AVC to measure informal caregivers' skills when caring for older stroke survivors at home

Results: The 32-item scale describes several aspects of informal caregiver's skills. The scale has eight factors: skill to feed/hydrate by nasogastric feeding, skill to assist the person in personal hygiene, skill to assist the person for transferring, skill to assist the person for positioning, skill

Estimating recruitment/retention

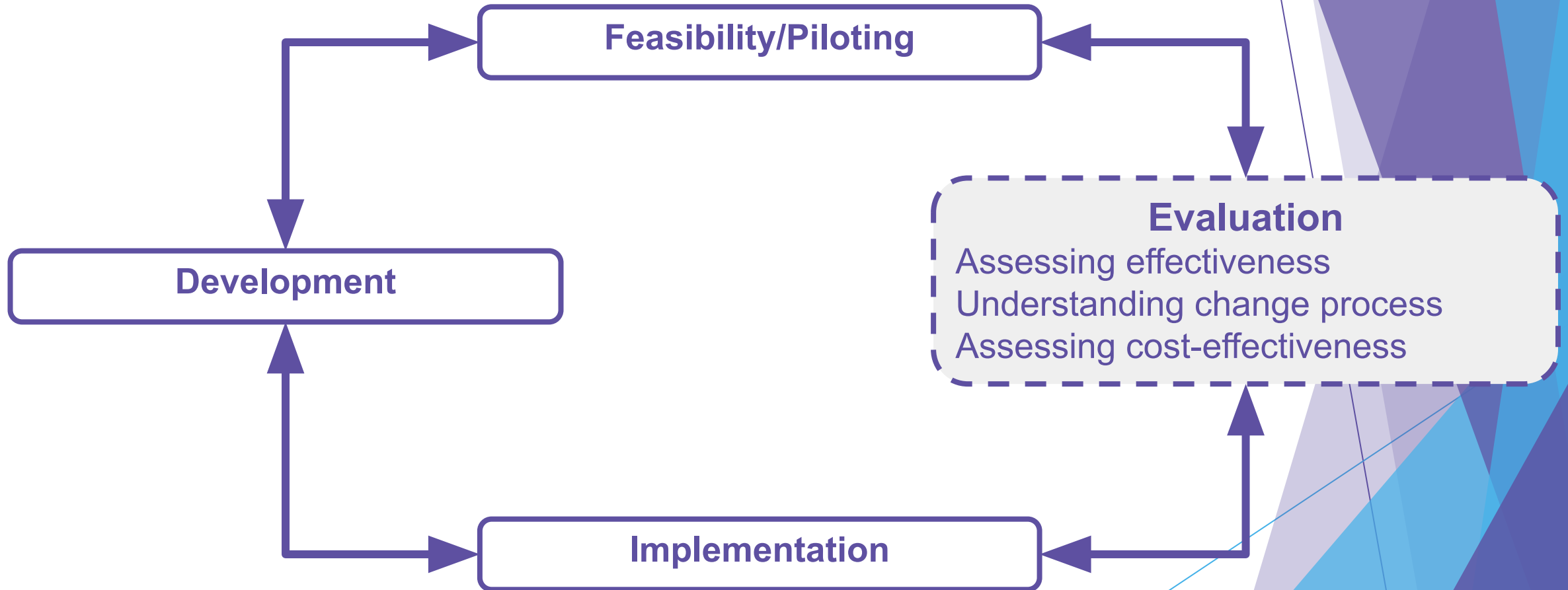
- ▶ Informal caregivers and older people stroke survivors post-discharge were referenced by Nursing staff from Community Health Units
- ▶ The study and research protocol have been approved by the Ethics Committee of Administração Regional de Saúde do Norte (ARS Norte) and has a number 44/2013 and is registered at clinicaltrials.gov with ID number NCT02074501

Determining the sample size

- ▶ Power of 0.8 and an alpha of 0.05 (95%)
- ▶ Control Group (CG n=79 T2) & Experimental Group (EG n=79 T2)
- ▶ Possible dropout rate of approximately 25% - 3 months after intervention



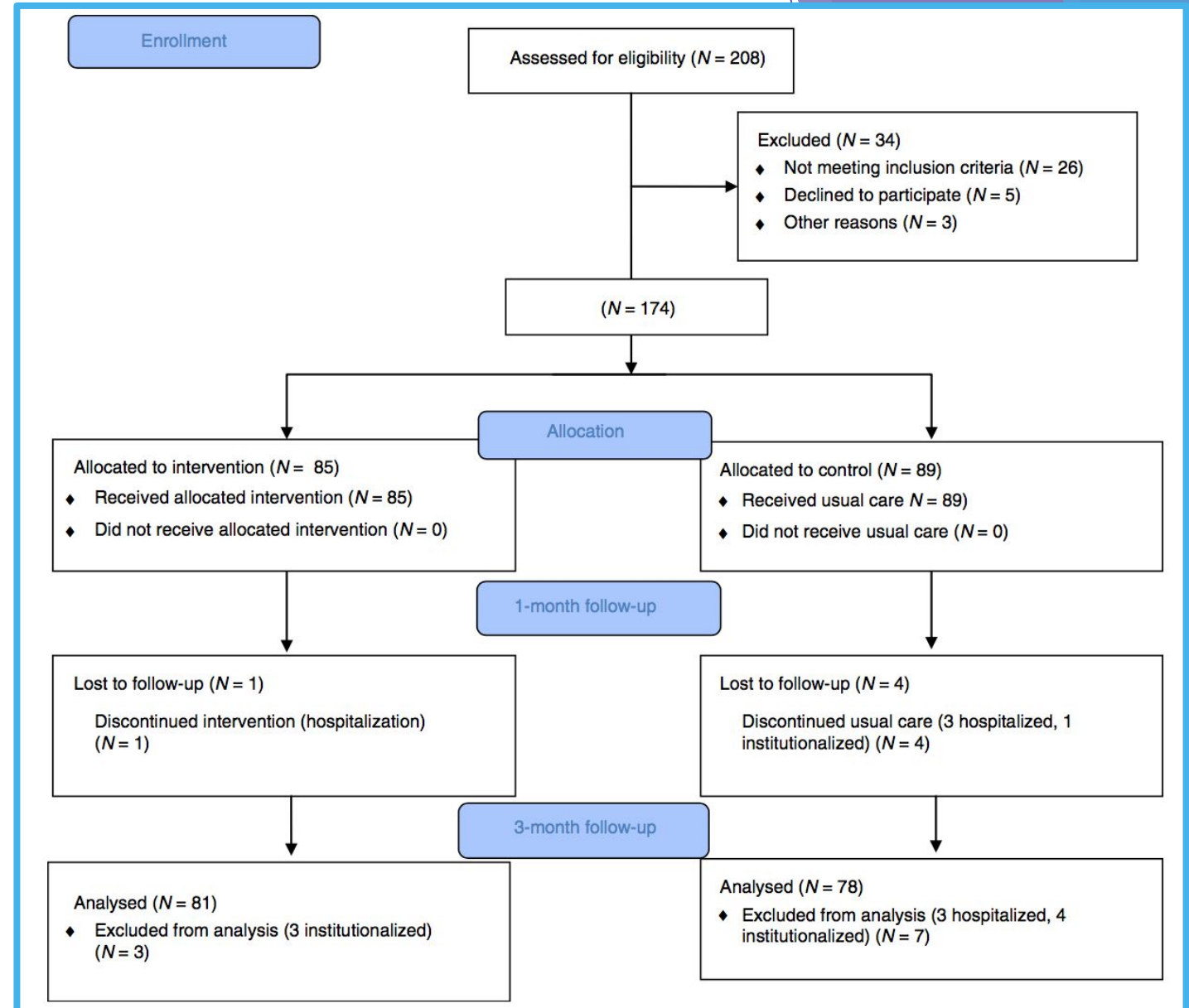
Phase III: Evaluation





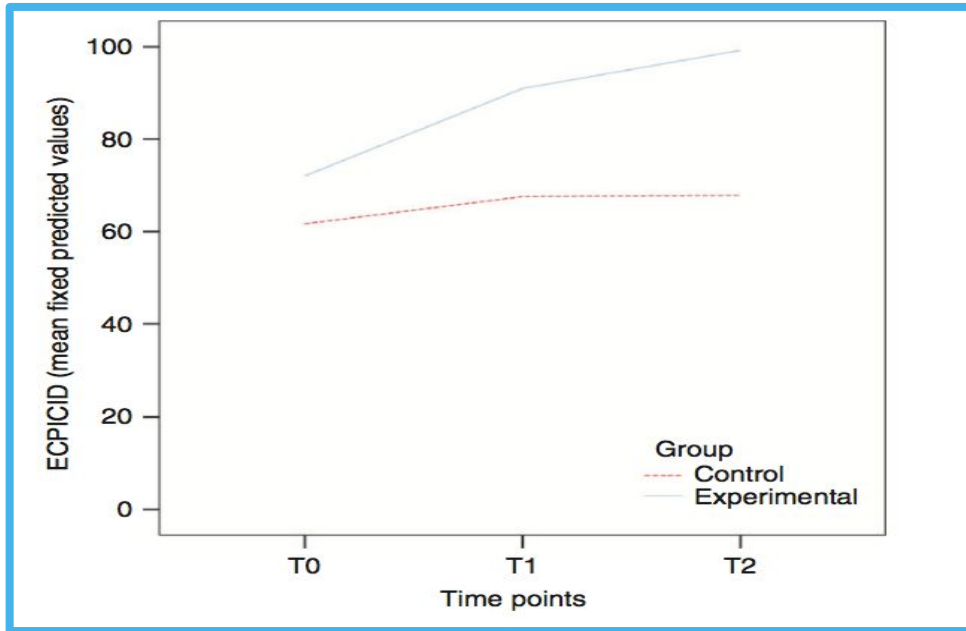
Logo: Intervention in Informal CAREgivers
who take care for older people after a stroke

► Flow diagram of the InCARE study

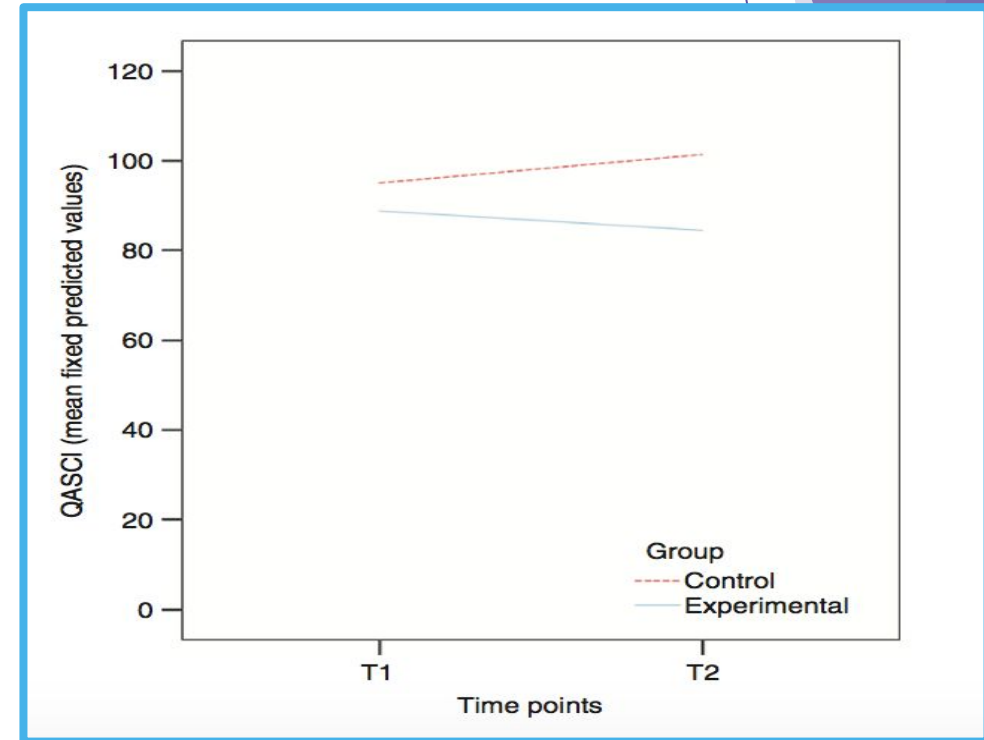


Results

Practical skills and Burden (informal caregivers)



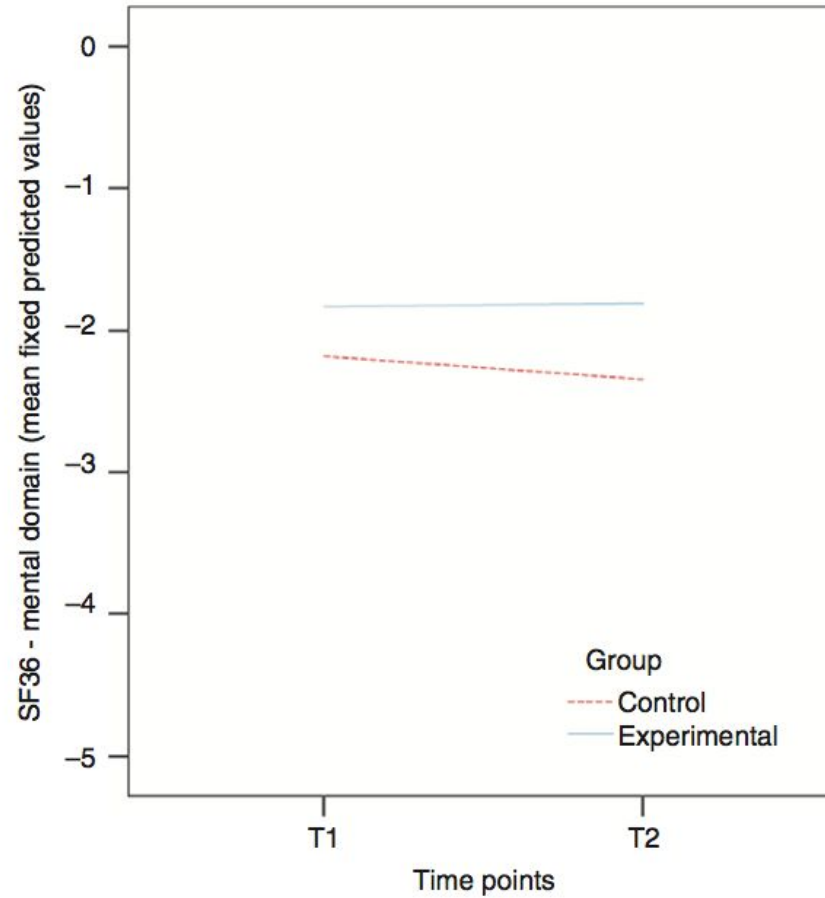
Estimated (evolution) of ECPCID-AVC depending on the group



Estimated (evolution) of QASCI depending on the group

Results

Mental Domain (informal caregivers)



Estimated (evolution) SF-36 (mental domain (depending on the group)

Results

Older stroke survivors' functionality

Multivariable binary logistic regression models.


	Group	Adjusted OR ^a	95% CI	p
T0-T1	Experimental	2.521	0.429–14.82	0.306
	Control (ref)	1	–	–
T0-T2	Experimental	1.626	0.316–8.351	0.561
	Control (ref)	1	–	–
T1-T2	Experimental	0.565	0.037–8.552	0.680
	Control (ref)	1	–	–

Legend: T0-first week; T1-first month; T2-third month.

ORIGINAL RESEARCH: CLINICAL TRIAL

WILEY **JAN**
Advancing Practice and Policy Worldwide through Research and Education

Training informal caregivers to care for older people after stroke: A quasi-experimental study

Odete Araújo^{1,2,3}  | Isabel Lage¹ | José Cabrita⁴ | Laetitia Teixeira^{3,5}

¹School of Nursing, University of Minho, Braga, Portugal

²Health Sciences Research Unit, Nursing (UICISA:E-UMinho), Portugal

³Research Group "AgeingC: Ageing Cluster", CINTESIS - Center for Health Technology and Services Research, Porto, Portugal

⁴Faculty of Pharmacy, University of Lisbon, Lisbon, Portugal

⁵Institute for the Biomedical Sciences Abel Salazar, University of Porto, Porto, Portugal

Abstract

Aims: This study aimed at evaluating whether training on practical skills involved in providing care reduces

their general health comorbidities.

Background: A substantial proportion of older people require stroke assistance to old people's situations as well as mental health.

Design: A quasi-experimental study.



ELSEVIER

Applied Nursing Research 55 (2020) 151280

Contents lists available at ScienceDirect

Applied Nursing Research

journal homepage: www.elsevier.com/locate/apnr



A quasi-experimental study of the effect of an intervention on older stroke survivors' functionality

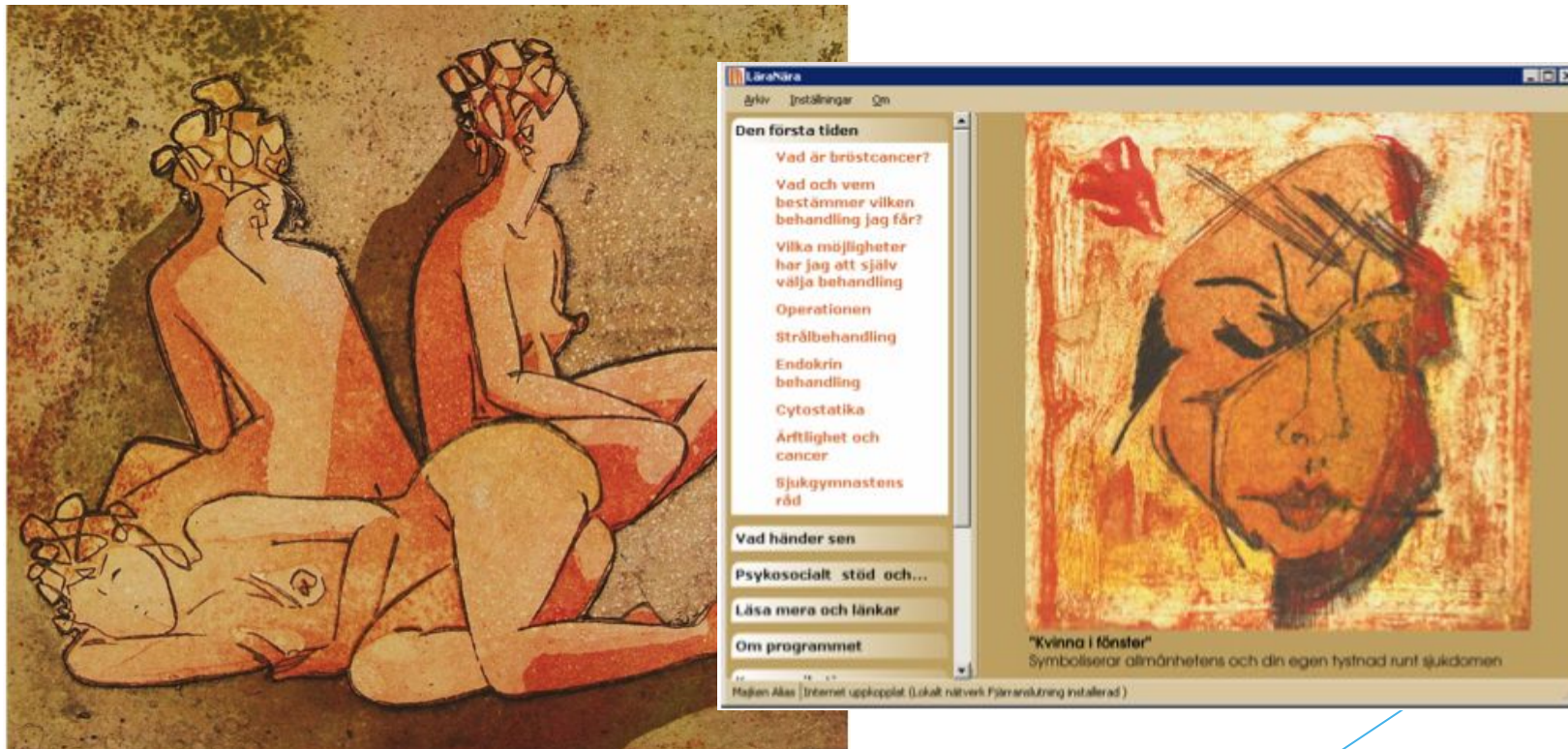
Odete Araújo (PhD, MSc, RMN)^{a,b,c,*}, Isabel Lage (PhD, MSc, RN)^d, José Cabrita (PhD, MSc)^e, Laetitia Teixeira (PhD, MSc)^f

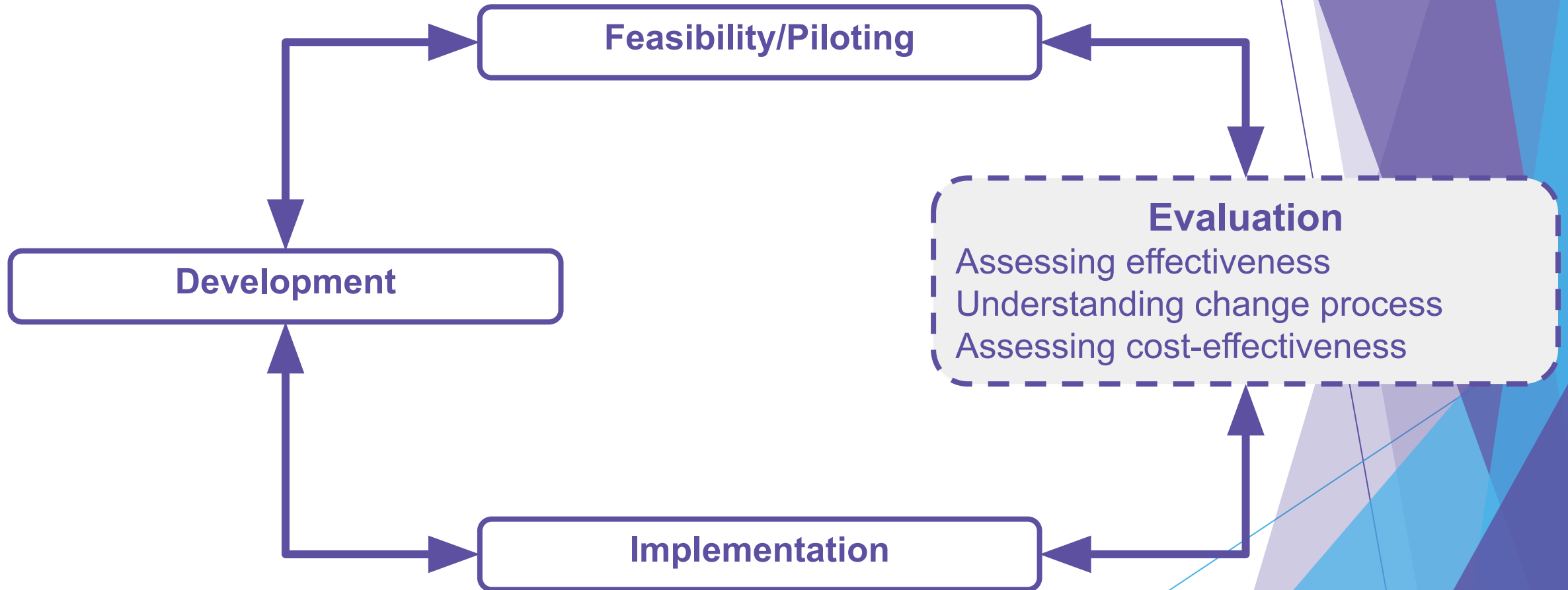


Reflections

- What did I learn from this experience?
- What would I do differently?

Web-based communication and support throughout the breast cancer journey



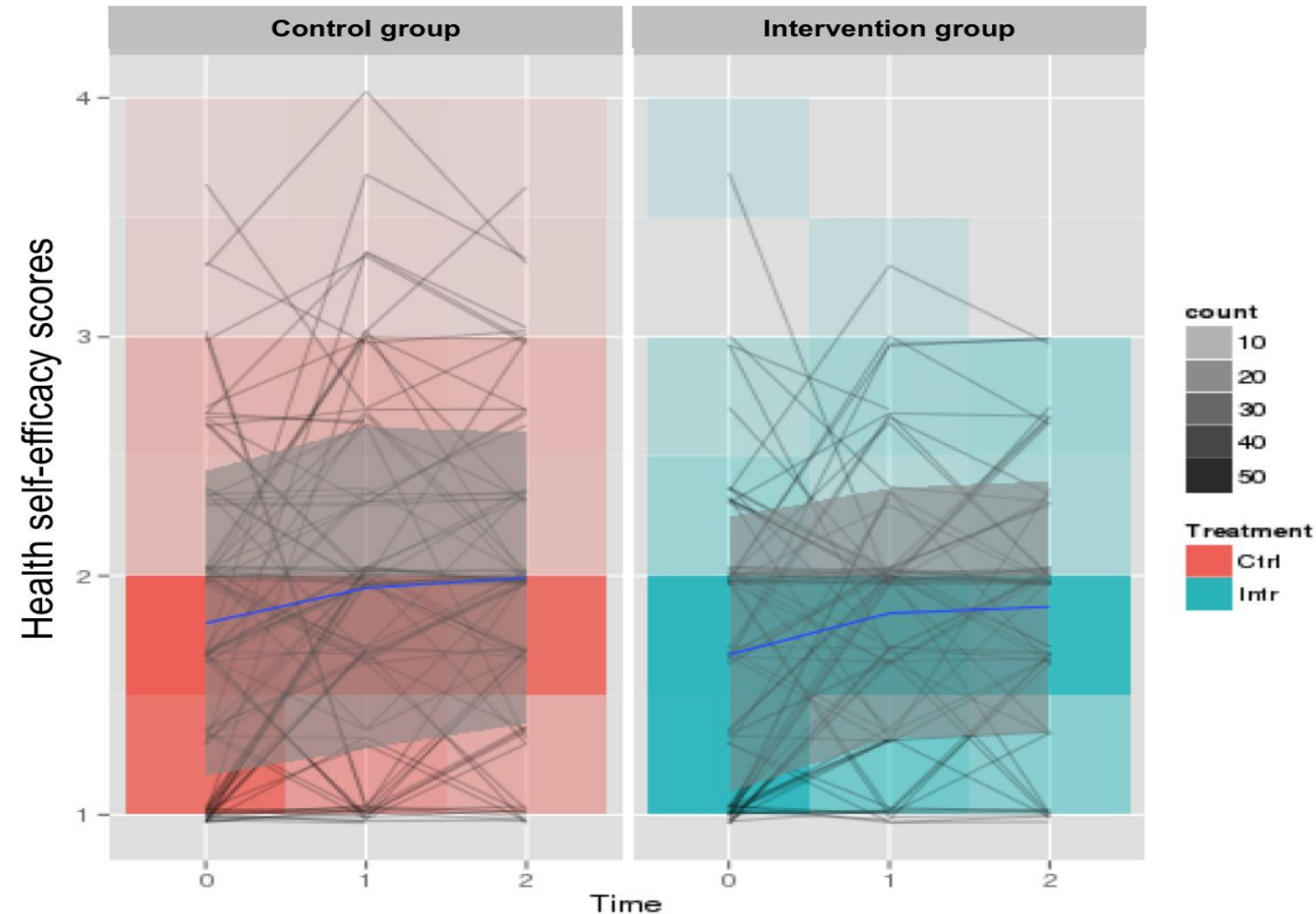


Methodology

- Longitudinal RCT (N=226)
- Three measurement points
- Multilevel analysis (CHESS, HADS)
- Multiple outcomes

Ventura et al. 2017

Results



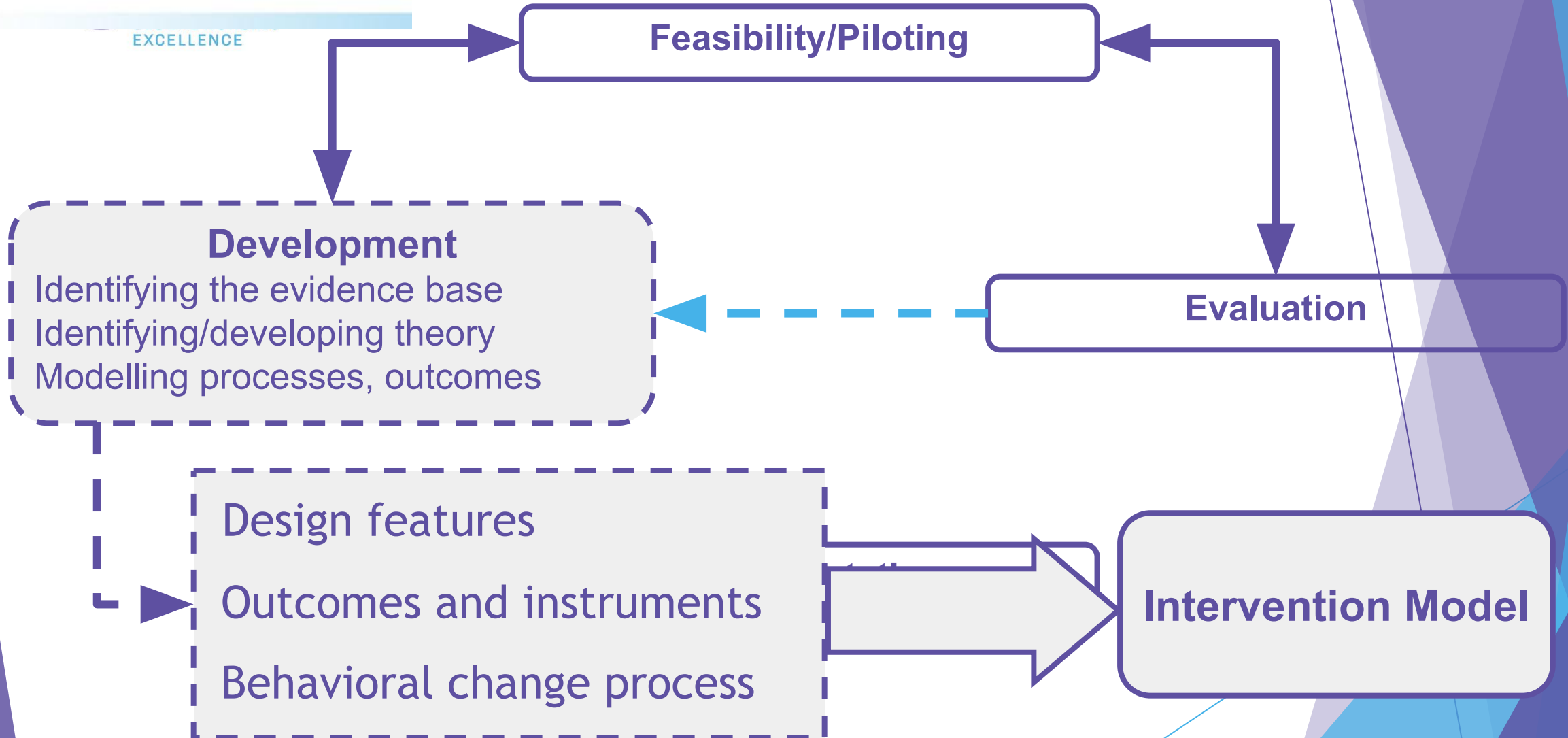
Evaluation of a web-based educational program for women diagnosed with breast cancer: why is the intervention effect absent?

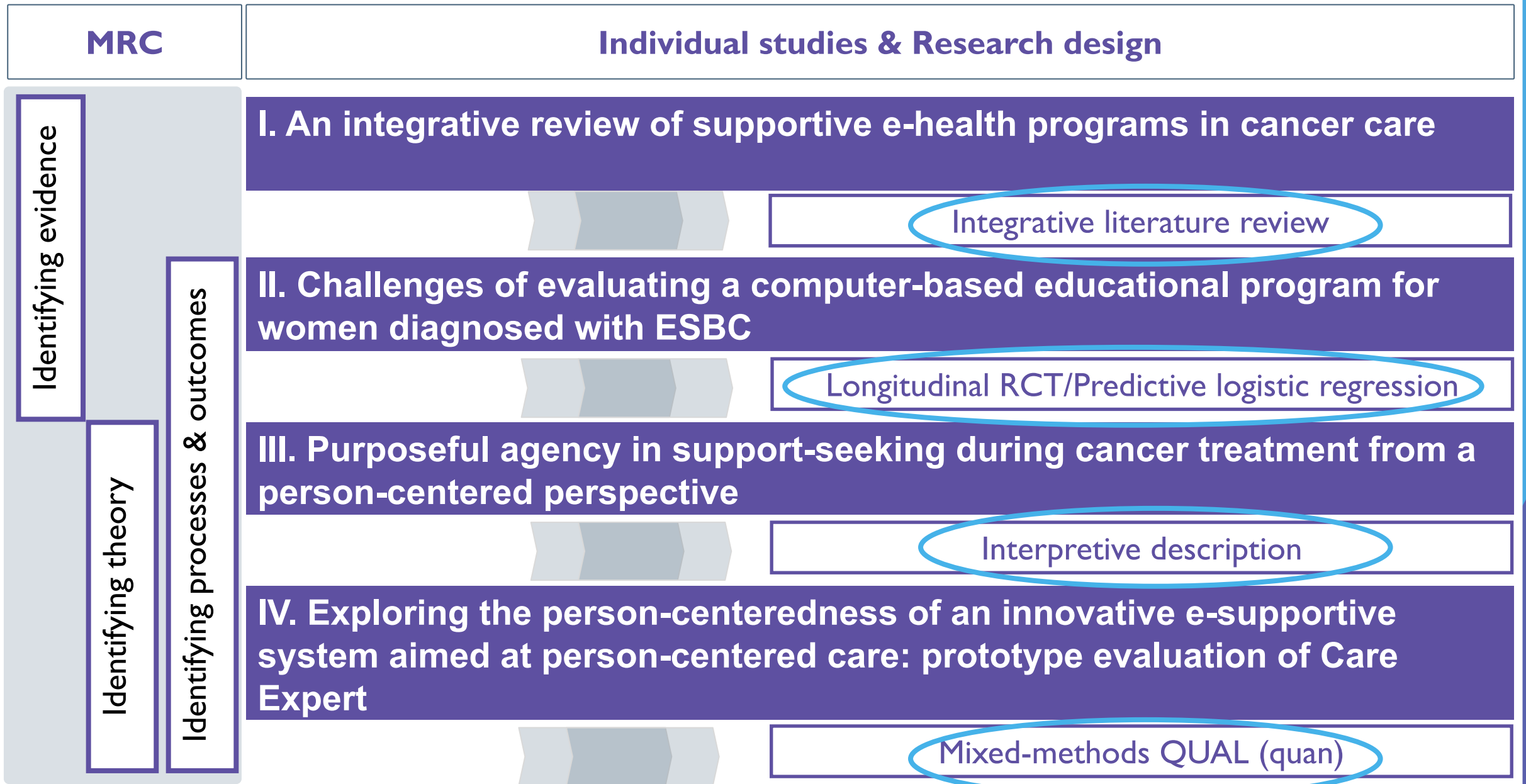
Ventura F¹ , Sawatzky R, Öhlén J, Karlsson P, Koinberg I

Author information ▶

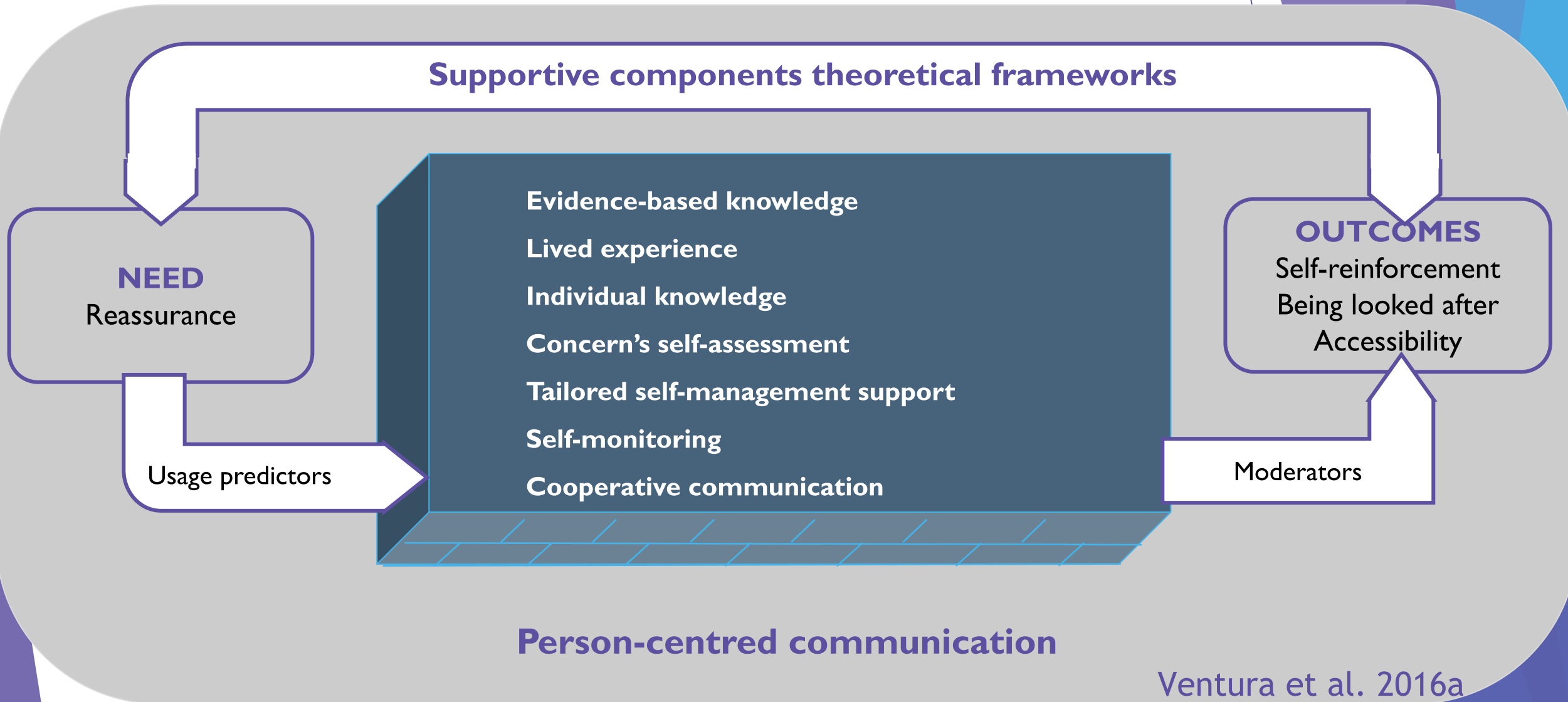
Studies in Health Technology and Informatics, 01 Jan 2013, 192:1132

PMID: 23920906

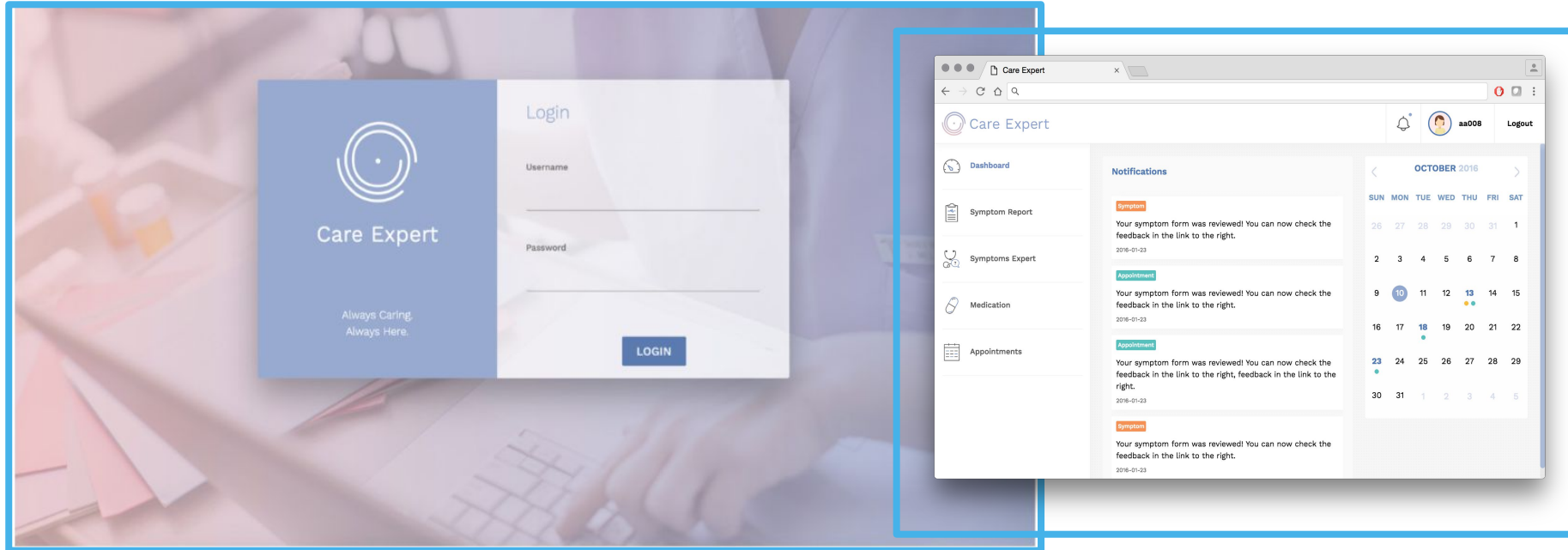




Explanatory Intervention Model



Care Expert



Ventura et al. 2016b

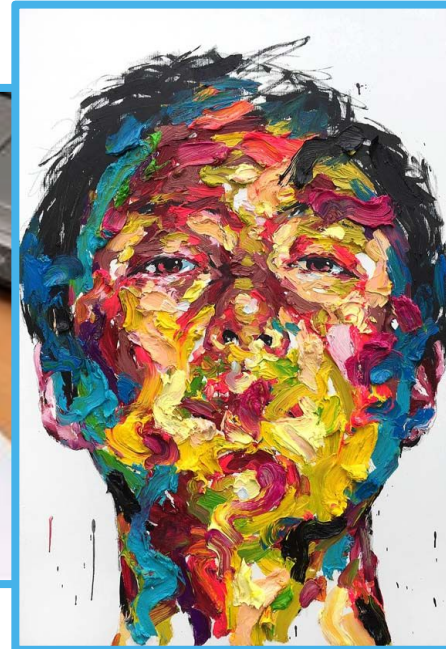
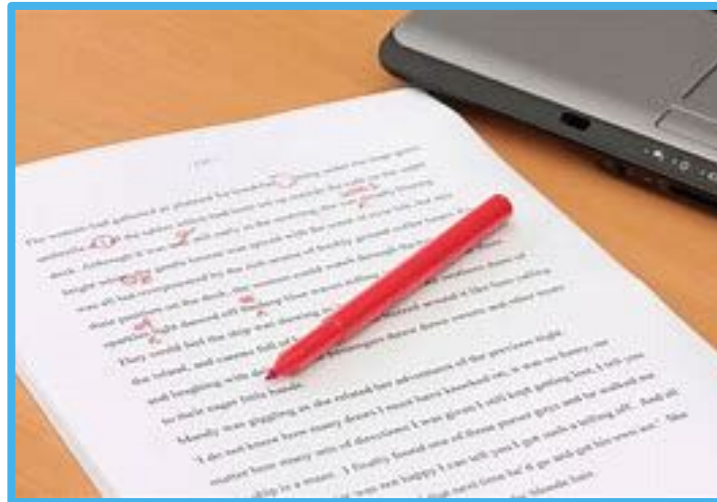
Person-centred supportive system

Lessons learned & Reflections

Start with the problem and not the solution...



... and report each phase



Accepted: 6 May 2016

DOI: 10.1111/ecc.12534

ORIGINAL ARTICLE

WILEY

European Journal of Cancer Care

Challenges of evaluating a computer-based educational programme for women diagnosed with early-stage breast cancer: a randomised controlled trial

F. Ventura MSc, PhD Candidate ¹ | R. Sawatzky PhD, Associate Professor ^{2,3} |
J. Öhlén PhD, Professor ^{1,4,5} | P. Karlsson PhD, MD, Professor ⁶ |
I. Koinberg PhD, RN, Senior Lecturer ^{1,4,7}

- Formal regular evaluation within a multidisciplinary team (incl. end-users)
- Continuous process evaluation

Take-home messages

Simplicity is a chimera





Proposed criteria for reporting the development and evaluation of complex interventions in healthcare (CReDECI): guideline development

Ralph Möhler^{a,*}, Gabriele Bartoszek^a, Sascha Köpke^b, Gabriele Meyer^a

^a School of Nursing Science, Faculty of Health, Witten/Herdecke University, Witten, Germany

^b Nursing Research Group, Institute of Social Medicine, University of Lübeck, Lübeck, Germany



De Silva et al. *Trials* 2014, **15**:267
<http://www.trialsjournal.com/content/15/1/267>

METHODOLOGY

Open Access

Theory of Change: a theory-driven approach to enhance the Medical Research Council's framework for complex interventions

Mary J De Silva^{1*}, Erica Breuer², Lucy Lee¹, Laura Asher¹, Neerja Chowdhary³, Crick Lund² and Vikram Patel^{1,3}

Cooper², David Gunnell³, Sally Haw⁴, Kenny Lawson⁵,
Ogilvie⁷, Mark Petticrew⁸, Barney Reeves⁹, Matt Sutton¹⁰

Arain et al. *BMC Medical Research Methodology* 2010, **10**:67
<http://www.biomedcentral.com/1471-2288/10/67>



BMC
Medical Research Methodology

CORRESPONDENCE

Open Access

What is a pilot or feasibility study? A review of current practice and editorial policy

Mubashir Arain¹, Michael J Campbell^{*1}, Cindy L Cooper¹ and Gillian A Lancaster²

RESEARCH METHODS & REPORTING

Evaluation of complex interventions: Medical Research Council guidance

Graham F Moore¹, Suzanne Audrey², Mary Barker³, Lyndal Bond⁴, Chris Bonell⁵, Wendy Hardeman⁶,
Laurence Moore⁷, Alicia O'Cathain⁸, Tannaze Tinati³, Daniel Wight⁷, Janis Baird³



Article

Realist complex intervention
science
principles
the M
fram
and e
inter

Adam F
Cardiff University, UK

Farah Jamal
UCL Institute of Education, UK

Team-work & Time



Together
Everyone
Achieves
More



Just dare to do it!



References

Araujo, O., Lage, I., Cabrita, J., & Teixeira, L. (2018). Training informal caregivers to care for older people after stroke: A quasi-experimental study. *Journal of advanced nursing*. 74:2196-2206. DOI: 10.1111/jan.13714

Araujo, O., Lage, I., Cabrita, J., & Teixeira, L. (2018). A quasi-experimental study of the effect of an intervention on older stroke survivors' functionality. *Applied Nursing Research*. 55:151280. doi.org/10.1016/j.apnr.2020.151280

Araujo, O., Lage, I., Cabrita, J., & Teixeira, L. (2015). Intervention in informal caregivers who take care of older people after a stroke (InCARE): Study protocol for a randomised trial. *Journal of advanced nursing*, 71(10), 2435-2443.

Araujo, O., Lage, I., Cabrita, J., & Teixeira, L. (2016). Development and psychometric properties of ECPICID-AVC to measure informal caregivers' skills when caring for older stroke survivors at home. *Scandinavian Journal of Caring Sciences*, 30(4), 821-829. <https://doi.org/10.1111/scs.12291>

Bakas, T. Farran, C.J. Austin, J.K. Given B.A. Johnson E.A., Williams L.S. (2009) Content validity and satisfaction with a stroke caregiver intervention program, *Journal of Nursing Scholarship*, 41 (4), pp. 368-75.

References

Campbell, M., Fitzpatrick, R., Haines, A., Kinmonth, A. L., Sandercock, P., Spiegelhalter, D., & Tyrer, P. (2000). Framework for design and evaluation of complex interventions to improve health. *Bmj*, 321(7262), 694-696.

Conn, V. S., M. J. Rantz, et al. (2001). "Focus on Research Methods: Designing Effective Nursing Interventions." *Research in Nursing and Health* 24: 433-442.

Corry M., Clarke M., While A.E. & Lalor J. (2013) Developing complex interventions for nursing: a critical review of key guidelines. *Journal of Clinical Nursing* 22(17-18), 2366-2386.

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *Bmj*, 337.

Davis SM., Jones, A. Jaynes, ME. Woodrum, KN. Canaday, M. Allen, L. Mallow, JA. (2020) Designing a multifaceted telehealth intervention for a rural population using a model for developing complex interventions in nursing, *BMC Nursing* 19 (9), p. 1-9.

References

De Geest, S., Zúñiga, F., Brunkert, T., Deschodt, M., Zullig, L. L., Wyss, K., & Utzinger, J. (2020). Powering Swiss health care for the future: implementation science to bridge “the valley of death”. *Swiss Medical Weekly*, 150(3738).

Forster, A., Brown, L., Smith, J., House, A., Knapp, P., Wright, J., & Young, J. (2012) Information provision for stroke patients and their care- givers. *Cochrane Database Systematic Review* 11: CD001919.

Forster, A., Dickerson, J., Young, J., Kalra, A., Nixon, J., Smithard, D., ... Farrin, A. (2013). A structured training programme for caregivers of inpatients after stroke (TRACS): A cluster randomised controlled trial and cost-effectiveness analysis. *The Lancet*, 382, 2069-2076.
[https://doi.org/10.1016/S0140-6736\(13\)61603-7](https://doi.org/10.1016/S0140-6736(13)61603-7)

Hallberg, I. R. (2009). Moving nursing research forward towards a stronger impact on health care practice?. *International journal of nursing studies*, 46(4), 407-412.

References

- Legg, L., Quinn, T., Mahmood, F., Weir, C., Tierney, J., Stott, D., . . . Langhorne, P. (2012). Nonpharmacological interventions for caregivers of stroke survivors. *Stroke: Journal of the American Heart Association*, 43, 30-31. <https://doi.org/10.1161/STROKEAHA.111.644914>
- Mallow, J.A. Theek, L.A. Walls, R. Theek, E. Mallow, B.K. (2016) Part A: The Development of ml SMART, a Nurse-Led Technology Intervention for Multiple Chronic Conditions. *Open Journal of Nursing*, 6, 303-308.
- Mallow, J.A. Theek, L.A. Walls, R. Theek, E. Mallow, B.K. (2016) Part B: The feasibility and acceptability of ml SMART, a Nurse-Led Technology Intervention for Multiple Chronic Conditions. *Open Journal of Nursing*, 6, 323-332.
- Richards, D. A., & Hallberg, I. R. (Eds.). (2015). *Complex interventions in health: an overview of research methods*.
- Shyu, Y.-I. L., Kuo, L.-M., Chen, M.-C., & Chen, S.-T. (2010). A clinical trial of an individualised intervention programme for family caregivers of older stroke victims in Taiwan. *Journal of Clinical Nursing*, 19, 1675-1685. <https://doi.org/10.1111/j.1365-2702.2009.03124.x>

References

- Van Meijel, B., C. Gamel, et al. (2004). "The development of evidence-based nursing interventions: methodological considerations." *Journal Advanced Nursing* 48(1): 84-92.
- Ventura, F., Sawatzky, R., Öhlén, J., Karlsson, P., & Koinberg, I. (2013). Evaluation of a web-based educational program for women diagnosed with breast cancer: why is the intervention effect absent?. *Studies in health technology and informatics*, 192, 1132-1132.
- Ventura, F. (2016a). Person-centred e-support. *Foundations for the development of nursing interventions in outpatient cancer care*.
- Ventura, F., Koinberg, I., Sawatzky, R., Karlsson, P., & Öhlén, J. (2016b). Exploring the person-centeredness of an innovative E-supportive system aimed at person-centered care: prototype evaluation of the care expert. *CIN: Computers, Informatics, Nursing*, 34(5), 231-239.
- Ventura, F., Sawatzky, R., Öhlén, J., Karlsson, P., & Koinberg, I. (2017). Challenges of evaluating a computer-based educational programme for women diagnosed with early-stage breast cancer: a randomised controlled trial. *European journal of cancer care*, 26(5), e12534.
- Whittemore, R. and M. Grey (2002). "The systematic development of nursing interventions." *Journal of Nursing Scholarship* 34(2): 115-120.

Thank you!



Filipa Ventura

filipaventura@esenfc.pt



Margarita Corry

CORRYM@tcd.ie



Odete Araújo

odete.araujo@ese.uminho.pt