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14 October 2012 Last updated at 20:02 ET

Sitting for long periods 'is bad for your health'

Sitting for h

myHealth

HOME DIET AND NUTRITION FITNESS

Sedentary behaviours increas

Annals of Internal Medicine

REVIEW

Sedentary Time and Its Association With Risk for Disease Incidence, Mortality, and Hospitalization in Adults

A Systematic Review and Meta-analysis

Aviroop Biswas, BSc; Paul I. Oh, MD, MSc; Guy E. Faulkner, PhD; Ravi R. Bajaj, MD; Michael A. Silver, BSc; Marc S. Mitchell, MSc; and David A. Alter, MD, PhD

- ✓**P** Among adults,
- ✓**I** does prolonged hours of sitting
- ✓**C** compared with not sitting
- ✓**O** increase the risk of incidence of disease, mortality and hospitalization, controlling for physical activity?

Session 2:
The place of pilot studies in process evaluation

Lehana Thabane
McMaster University

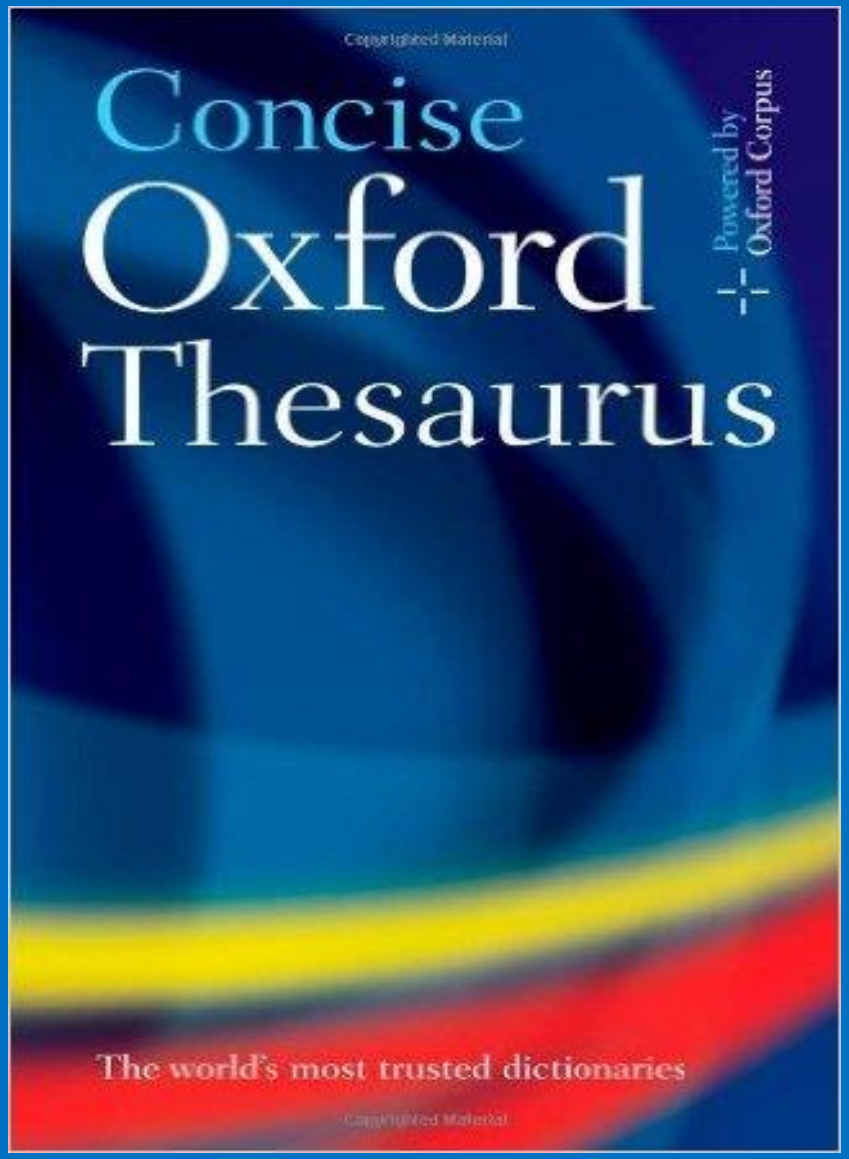
Paris
November 16, 2016

France REcherche Nord & sud Sida-hiv Hépatites
Agence autonome de l'Inserm
Institut de Recherche en Santé Publique IReSP
INSTITUT NATIONAL DU CANCER
aviesan alliance nationale pour les sciences de la vie et de la santé
ITMO Cancer
ITMO Immunologie, Inflammation, Infectiologie et Microbiologie
ITMO Santé publique

Dictionary Definition

Concise Oxford Thesaurus, 2nd Edition. Oxford University Press: Oxford, England, 2002

- ✓ **Pilot (project)**
  - ❑ Experimental
  - ❑ Exploratory
  - ❑ Test
  - ❑ Preliminary
  - ❑ Trial
  - ❑ Try out

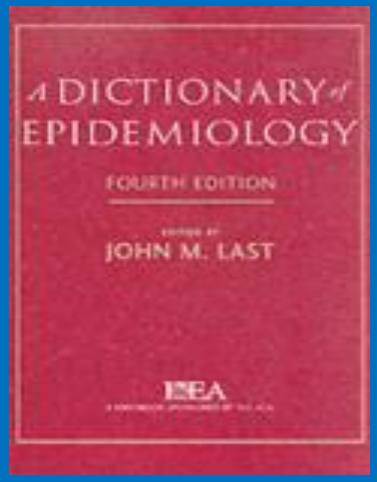


Synonymous terms

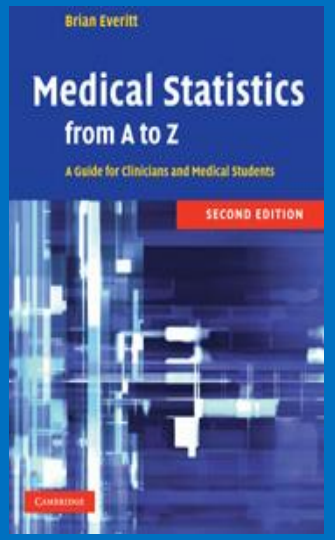
- ✓Feasibility study
- ✓Vangard study
- ✓Dress rehearsal
- ✓Pre-study

Stats/Epi Dictionary Definitions

- A small-scale ***test of the methods and procedures to be used on a larger scale*** if the pilot study demonstrates that the methods and procedures can work



- Small-scale investigation designed to ***test the feasibility of methods and procedures*** for later use on a large scale or ***to search for possible effects and associations*** that may be worth following up in a subsequent larger study



Definitions

- A trial study carried out before a research design is finalised in order **to assist in defining the research question** or **to test the feasibility, reliability and validity of the proposed study design**:
  - www.cirem.org.uk/definitions.html
- A smaller version of a study is carried out before the actual investigation is done. Researchers use information gathered in pilot studies **to refine or modify the research methodology for a study and to develop large-scale studies**:
  - www.mh.state.oh.us/offices/oper/glossary.html
- A project that is done, **to test the basic protocols and design to be used in a research study**. It is at this stage that the variables are refined to produce results that are meaningful:
  - www.eskimo.com/~hwa/glossary/glo_p.html
- A small study **carried out before a large-scale study** in order **to try out a procedure or to test a principle**:
  - www.vnet5.org/reg/handbook/glossary.html

What is the current practice of pilot studies?

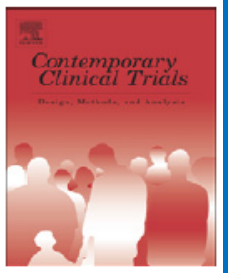
Different views on definitions: Pilot vs Feasibility study/trial

Contemporary Clinical Trials 38 (2014) 130–133

Contents lists available at ScienceDirect

Contemporary Clinical Trials

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



Pilot and feasibility studies: Is there a difference from each other and from a randomised controlled trial?

Amy L. Whitehead, Benjamin G.O. Sully, Michael J. Campbell *

Design, Trials and Statistics Group, School of Health and Related Research, University of Sheffield, Regent Court, 30 Regent Street, Sheffield S1 4DA, UK

- ✓ No consensus on definitions of pilot or feasibility studies
- ✓ Some take the two to be the same; others think they are different

Crit Care Med 2009 Vol. 37, No. 1 (Suppl.)

The design and interpretation of pilot trials in clinical research in critical care

Donald M. Arnold, MD, MSc (Epid); Karen E. A. Burns, MD, MSc (Epid);
Neill K. J. Adhikari, MD, MSc (Epid); Michelle E. Kho, BHSc (PT); Maureen O. Meade, MD, MSc (Epid);
Deborah J. Cook, MD, MSc (Epid); for the McMaster Critical Care Interest Group

Key message

- ✓ Multiple terms used without clear distinction
  - ❑ Pilot work
  - ❑ Pilot study
  - ❑ Feasibility study
  - ❑ Pilot trial

Thabane et al. BMC Medical Research Methodology 2010, 10:1
http://www.biomedcentral.com/1471-2288/10/1

BMC Medical Research Methodology

COMMENTARY Open Access

A tutorial on pilot studies: the what, why and how

Lehana Thabane[1,2*], Jinhui Ma[1,2], Rong Chu[1,2], Ji Cheng[1,2], Afisi Ismaila[1,3], Lorena P Rios[1,2], Reid Robson[3], Marroon Thabane[1,4], Lora Giangregorio[5], Charles H Goldsmith[1,2]

We use pilot and feasibility study interchangeably

- Reports don't mention that they are done to inform main studies
- Variations in journal editorial policies about pilot studies

Journal of Evaluation in Clinical Practice, 10, 2, 307–312

Design and analysis of pilot studies: recommendations for good practice

Gillian A. Lancaster MSc PhD,[1] Susanna Dodd MSc[2] and Paula R. Williamson PhD[3]
[1]Lecturer in Medical Statistics, [2]Research Assistant in Medical Statistics [3]Senior Lecturer in Medical Statistics, Department of Mathematical Sciences, University of Liverpool, Liverpool, UK

- ✓ Surveyed 7 journals: BMJ, Lancet, JAMA, NEJM, BJC, BJOG, BJS
  - ❑ Searched "pilot" or "feasibility" in title or abstract in 2000--2001
  - ❑ 90 unique studies: **4/90 specifically stated that the pilot was in preparation for a bigger RCT**
- ✓Contacted the editors of the 7 journals screened
  - ❑ 4/7 indicated **no publication policy**
  - ❑ 1/7 indicated the journal **did not publish pilot studies**

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 Arain[1], Michael J Campbell*[1], Cindy L Cooper[1] and Gillian A Lancaster[2]

- ✓ Repeated Lancaster *et al* study for publications in 2007-8
- ✓ 54 unique studies
- ✓ contacted the editors of the journals screened
  - ❑ 4/7 indicated **no publication policy**…

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association®

Pilot Trials in Clinical Research: Of What Value Are They?

Joseph Loscalzo

Circulation. 2009;119:1694-1696

Editorial message

- ✓41 pilot trials published in Circulation since 2004
- ✓For most, **editors requested the term 'pilot' be added to the title to acknowledge small size and lack of generalizibility**

Reasons for conducting pilot or feasibility studies may be clinical, procedural or methodological

Assessing feasibility of procedures and methods

Samaan *et al. Pilot and Feasibility Studies* (2015) 1:39
DOI 10.1186/s40814-015-0034-y

PILOT AND FEASIBILITY STUDIES

STUDY PROTOCOL Open Access

A pragmatic pilot randomized trial to investigate the effectiveness of behavioural activation group therapy in reducing depressive symptoms and improving quality of life in patients with depression: the BRAVE pilot trial protocol

Zainab Samaan[1,2,3,4*], Kathryn Litke[2], Kathleen McCabe[1,2], Brittany Dennis[3], Jeff Whattam[2], Laura Garrick[2], Laura O'Neill[1,2], Terri Ann Tabak[1,2], Scott Simons[2], Sandra Chalmers[2], Brenda Key[1,2], Meredith Vanstone[3], Feng Xie[3], Gordon Guyatt[3,5] and Lehana Thabane[3,6,7,8,9]

Feasibility Outcomes:

- ❑ Recruitment rates
- ❑ Retention rate
- ❑ Data completeness rates
- ❑ Feedback on intervention
- ❑ Resources required to conduct main study

Assessing feasibility of procedures and methods

Johnstone *et al. Pilot and Feasibility Studies* (2015) 1:19
DOI 10.1186/s40814-015-0013-3

PILOT AND FEASIBILITY STUDIES

STUDY PROTOCOL Open Access

*Pro*biotics: Prevention of *S*evere *P*neumonia and *E*ndotracheal Colonization *T*rial—PROSPECT: protocol for a feasibility randomized pilot trial

Jennie Johnstone[1,2,3], Maureen Meade[4,5], John Marshall[3,6,7], Daren K Heyland[8], Michael G Surette[4], Dawn ME Bowdish[9], Francois Lauzier[10], Lehana Thebane[5,11], Deborah J Cook[4,5*] and For the PROSPECT Investigators and the Canadian Critical Care Trials Group

Feasibility Outcomes:

- ❑ Recruitment rates
- ❑ high protocol adherence,
- ❑ minimal contamination, and
- ❑ an acceptable VAP (ventilator associated pneumonia) rate.

Assessing feasibility of procedures and methods

JAMDA 15 (2014) 943–945

ELSEVIER

JAMDA

journal homepage: www.jamda.com

Brief Report

Implementing a Knowledge Translation Intervention in Long-Term Care: Feasibility Results From the Vitamin D and Osteoporosis Study (ViDOS)

Courtney C. Kennedy PhD [a], Lehana Thabane PhD [b], George Ioannidis PhD [a], Jonathan D. Adachi MD, FRCPC [a], Alexandra Papaioannou MD, MSc, FRCP (C) FACP [a,*] on behalf of the ViDOS Investigators

[a] Department of Medicine, McMaster University, Hamilton, ON, Canada
[b] Department of Epidemiology and Biostatistics, McMaster University, Hamilton, ON, Canada

Feasibility Outcomes:

- ❑ Recruitment rates
- ❑ Retention rates
- ❑ Participation rate
- ❑ Completion of action plans, feedback reports
- ❑ Completeness of data

Criteria for determining success of feasibility assessment

Key Points

- **It is always important to state the criteria for success or feasibility**

- **Outcome can be**
  - ✓ *Stop* - main study not feasible;
  - ✓ *Continue, but modify protocol* – feasible with modifications
  - ✓ *Continue without modifications* – feasible asis
  - ✓ *Continue without modifications, but monitor closely* – feasible with close monitoring

- **The criteria should be based on key primary feasibility aims**

Pai *et al. Implementation Science* 2013, **8**:1
http://www.implementationscience.com/content/8/1/1

IMPLEMENTATION SCIENCE

RESEARCH Open Access

Strategies to enhance venous thromboprophylaxis in hospitalized medical patients (SENTRY): a pilot cluster randomized trial

Menaka Pai[1,3*], Nancy S Lloyd[1], Ji Cheng[2,4], Lehana Thabane[2,4,5], Frederick A Spencer[1], Deborah J Cook[1,2], R Brian Haynes[1,2], Holger J Schünemann[1,2] and James D Douketis[1,2]

Criteria for success of feasibility

- ✓ **Objective:**
  - ❑ To determine adherence rates to the risk assessment model and standardized order form
- ✓ **Criterion for success:**
  - ❑ '*definitely feasible*' if the risk assessment form is completed for ≥70% of eligible patients.

JAMDA 15 (2014) 943–945

JAMDA

journal homepage: www.jamda.com

Brief Report

Implementing a Knowledge Translation Intervention in Long-Term Care: Feasibility Results From the Vitamin D and Osteoporosis Study (ViDOS)

Courtney C. Kennedy PhD [a], Lehana Thabane PhD [b], George Ioannidis PhD [a], Jonathan D. Adachi MD, FRCPC [a], Alexandra Papaioannou MD, MSc, FRCP (C) FACP [a,*] on behalf of the ViDOS Investigators

[a] Department of Medicine, McMaster University, Hamilton, ON, Canada
[b] Department of Epidemiology and Biostatistics, McMaster University, Hamilton, ON, Canada

Table 1
Feasibility Results for the ViDOS Trial

Measure	Target, %	Observed, %	Description
Recruitment	40	22	▪ Acceptance rate was low; took several months ▪ Accomplished target sample size (n = 40)
Retention	80	63	▪ 7 INT homes withdrew active participation.
Participation	80	25–100	▪ Overall: n = 164 participants from 12 active INT homes; 56% attended at least 2 meetings* **Key roles:** ▪ ≥ 2 meetings: Director/assistant director of care†; pharmacist = 100%; medical director† = 92% ▪ 3 meetings: Director/assistant director† = 83%; pharmacist = 92%; medical director† = 25%
Action plans	80	100	▪ Completed by all homes
Feedback reports	80	100	▪ Reviewed at all INT sessions (months 0, 6, 12)
Data completion	80	86–92	▪ All spreadsheets: 86% control/92% INT homes

Key messages

- Pilot studies provide a good opportunity to assess feasibility of large full-scale evaluation studies
- **It can enhance the success probability of the main study**

- ✓ **Most are not well designed**
  - No clear feasibility objectives
  - No clear rationale for piloting
  - No clear analytic plans
  - No clear criteria for success of feasibility
- ✓ **Most are not reported/published**
- ✓ **They should be scrutinized the same way as full scale studies/RCTs**
  - Require registration
  - They should also be published/reported in peer-review journals

African Proverb (Ashanti, Ghana)

You never test the depth of a river with both feet

What's new in pilot trials?

The CONSORT extension to pilot trials: New Initiative

Pilot CONSORT Working Group

Sandra Eldridge

Queen Mary University of London

Michael Campbell

The University Of Sheffield.

Sally Hopewell

UNIVERSITY OF OXFORD

Lehana Thabane

McMaster University

Christine Bond

UNIVERSITY OF ABERDEEN

Gillian Lancaster

LANCASTER UNIVERSITY

Our first paper

1. Definitions for feasibility and pilot
2. Defining the conceptual framework

PLOS ONE

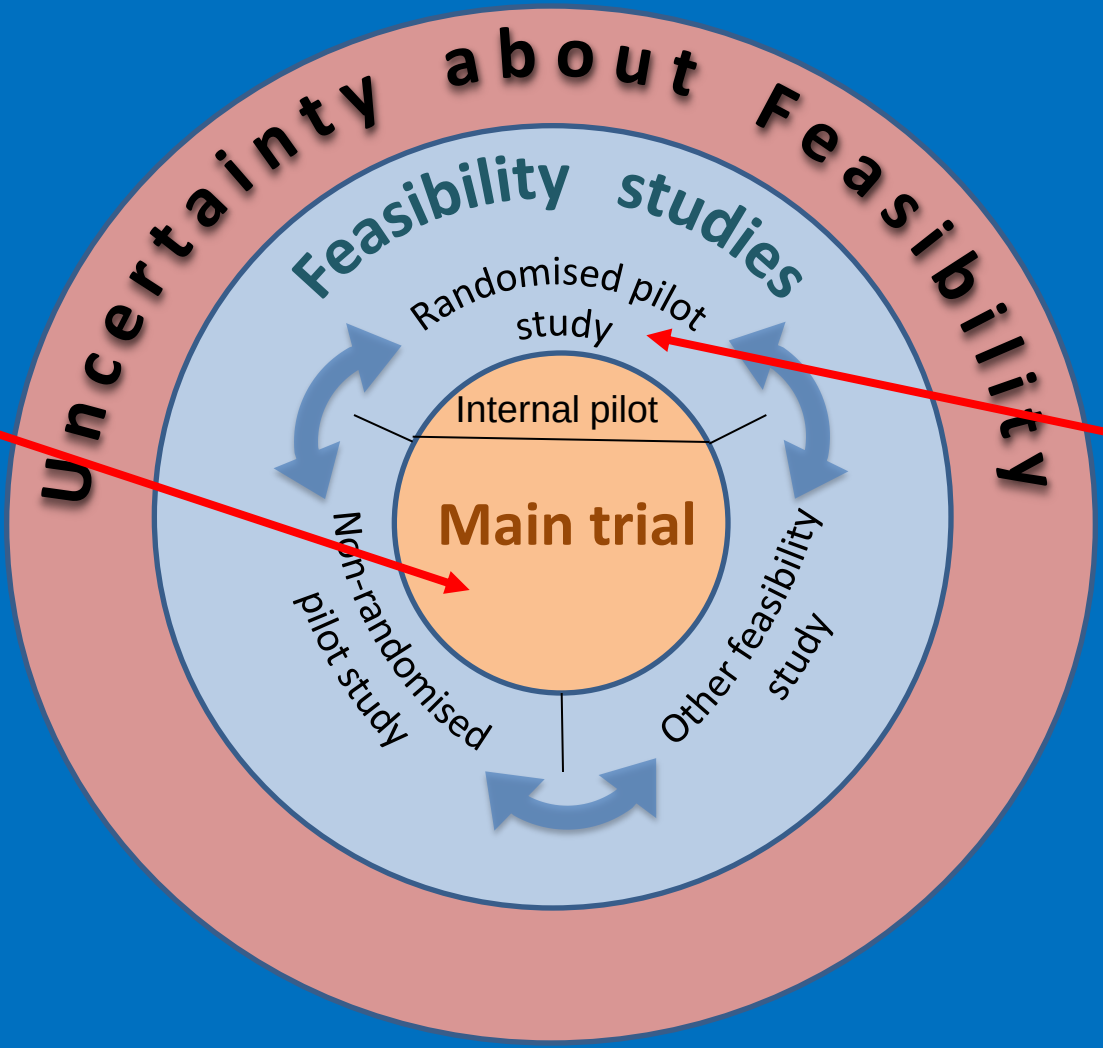
RESEARCH ARTICLE

Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework

Sandra M. Eldridge[1]*, Gillian A. Lancaster[2], Michael J. Campbell[3], Lehana Thabane[4], Sally Hopewell[5], Claire L. Coleman[1], Christine M. Bond[6]

The frameworks and implications for reporting randomized pilot trials

CONSORT statement for randomized trials



CONSORT extension for pilot randomized trials

Our second paper

Describing the methods and processes for developing the guideline

Thabane *et al. Pilot and Feasibility Studies* (2016) 2:25
DOI 10.1186/s40814-016-0065-z

Pilot and Feasibility Studies

METHODOLOGY Open Access

Methods and processes for development of a CONSORT extension for reporting pilot randomized controlled trials

Lehana Thabane[1*], Sally Hopewell[2], Gillian A. Lancaster[5], Christine M. Bond[6], Claire L. Coleman[3], Michael J. Campbell[4] and Sandra M. Eldridge[3]

Our third paper

The CONSORT extension to pilot RCT guideline

Eldridge *et al. Pilot and Feasibility Studies* (2016) 2:64
DOI 10.1186/s40814-016-0105-8

Pilot and Feasibility Studies

RESEARCH Open Access

CONSORT 2010 statement: extension to randomised pilot and feasibility trials

Sandra M. Eldridge[1*], Claire L. Chan[1], Michael J. Campbell[2], Christine M. Bond[3], Sally Hopewell[4], Lehana Thabane[5], Gillian A. Lancaster[6] and on behalf of the PAFS consensus group

RESEARCH METHODS AND REPORTING

OPEN ACCESS

CONSORT 2010 statement: extension to randomised pilot and feasibility trials

Sandra M Eldridge,[1] Claire L Chan,[1] Michael J Campbell,[2] Christine M Bond,[3] Sally Hopewell,[4] Lehana Thabane,[5] Gillian A Lancaster[6] on behalf of the PAFS consensus group

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PILOT AND FEASIBILITY STUDIES

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Pilot and Feasibility Studies is an open access, peer-reviewed, online journal that encompasses all aspects of the design, conduct and reporting of pilot and feasibility studies in biomedicine. The journal publishes research articles that are intended to directly influence future clinical trials, as well as protocols, commentaries and methodology articles. The journal also ensures that the results of all well-conducted, peer-reviewed, pilot and feasibility studies are published, regardless of outcome or significance of findings.

Editor in Chief

Gillian Lancaster, University of Lancaster

Editorial Board | Instructions for authors | FAQ

There will be 10 minutes each from:

Pilot study or evaluability assessment?

Louise Potvin, Universié de Montréal

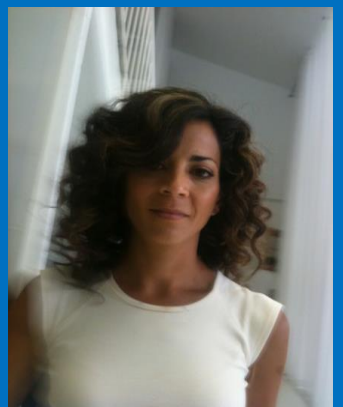
Exploring intervention mechanisms before piloting a smoking cessation prevention program: the RESIST study

Laetitia Minary,
Université de Lorraine et
Université de Montréal

Joëlle Kivits,
Université de Lorraine

Pilot study and process evaluation: a happy marriage?

Kareen Nour, Ecole de Santé Publique
de l'Université de Montréal



Session 2 discussions

- The place of pilot studies in process evaluation: objectives, contribution
  - co-construction of a theory
  - validation/invalidation of a planned theory
  - evaluation of the mechanisms

- pilot studies to contrast the effects of context or to test different modalities of interventions—in terms of
  - feasibility
  - recruitment
  - inclusion
  - participation