SUNG KYUN KWAN UNIVERSITY

World congress of Psycho-oncology 2015 Review

Psychosocial Intervention Research: Principles for Rigorous Design and Tips for Successful Conduct

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Psychosocial Intervention Research

- Principles of **study designs**
- Determining **sample size**
- Choice of appropriate **assessment measures**
- Approaches to **analyses**
- How to deal with **missing data**

Trends of Psycho-oncologic intervention

- The scope of the problem
  - Increased burden of cancer
  - Consumer expectation
  - Limited workforce and burnout amongst clinician
  - Global economic prospects

➢ **Supportive care intervention use minimal health resource !**

Trends of Psycho-oncologic intervention

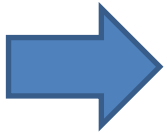
- Supportive care intervention
  - Empower patients and family
  - Recognize family and social circumstances
  - Account for individual needs
  - Patient/family centered

Trends of Psycho-oncologic intervention

2013 IPOS

Current active issues
- Survivorship
- Distress screening

Potential area
- Minority populations
- Quality of care in practice
- Communication Skills
- E-Health



2015 IPOS

Current active issues
- New populations
- Self-management strategy
- Quality of care in practice
- Patient reported outcome
- Research quality improve

Potential area
- Physician's burden
- Find out underserved parts
- Wearable devices

Introduction

Acta Oncologica, 2015; Early Online: 1–8

informa
healthcare

ORIGINAL ARTICLE

Effective, clinically feasible and sustainable: Key design features of psycho-educational and supportive care interventions to promote individualised self-management in cancer care

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Research, University of Queensland, Queensland, Australia

ABSTRACT

As the global burden of cancer increases healthcare services will face increas
of these patients, their families and the communities in which they live. This
need where direct clinical contact may be constrained or not readily availabl
and skills to manage their illness outside of the hospital setting within their
Aim. To propose a framework for the development and delivery of psycho-edu
drawing on theoretical principles of behaviour change and evidence-based int
ence in developing and testing complex interventions in oncology.
Approach. At the core of this intervention framework are considerations of
cater for individuals' unique needs; to place minimal demands on the healt
disseminated into usual care if successful. There are seven key features: 1) Ta
to unique individual needs; 3) Promotion of patient self-management of
4) Efficient delivery of the intervention; 5) Training and adherence to protocol
based; 7) Confirming stakeholder acceptability of the intervention.
Application. A case study of a randomised controlled trial which tested p
using this framework is presented. These interventions were designed to cater
self-management while placing minimal demands on the acute health care se
Discussion. Innovative ways to realise the potentially major impact that
interventions can have on psychological morbidity, coping, symptoms and qu
are needed. This framework, which is driven by theory, evidence, and experi
tions are effective, clinically feasible and sustainable.

Cancer is the leading cause of burden of disease in the world, accounting for nearly one-fifth of the total disease burden [1]. The diagnosis and subsequent treatment of cancer is a major life stress that is followed by a range of well described psychological, social, physical, sexual, spiritual and practical difficulties [2]. The demand for oncology services in the US was estim
2020 [3]. In t
care services,
than they are
With the
public spendi
care, healthca

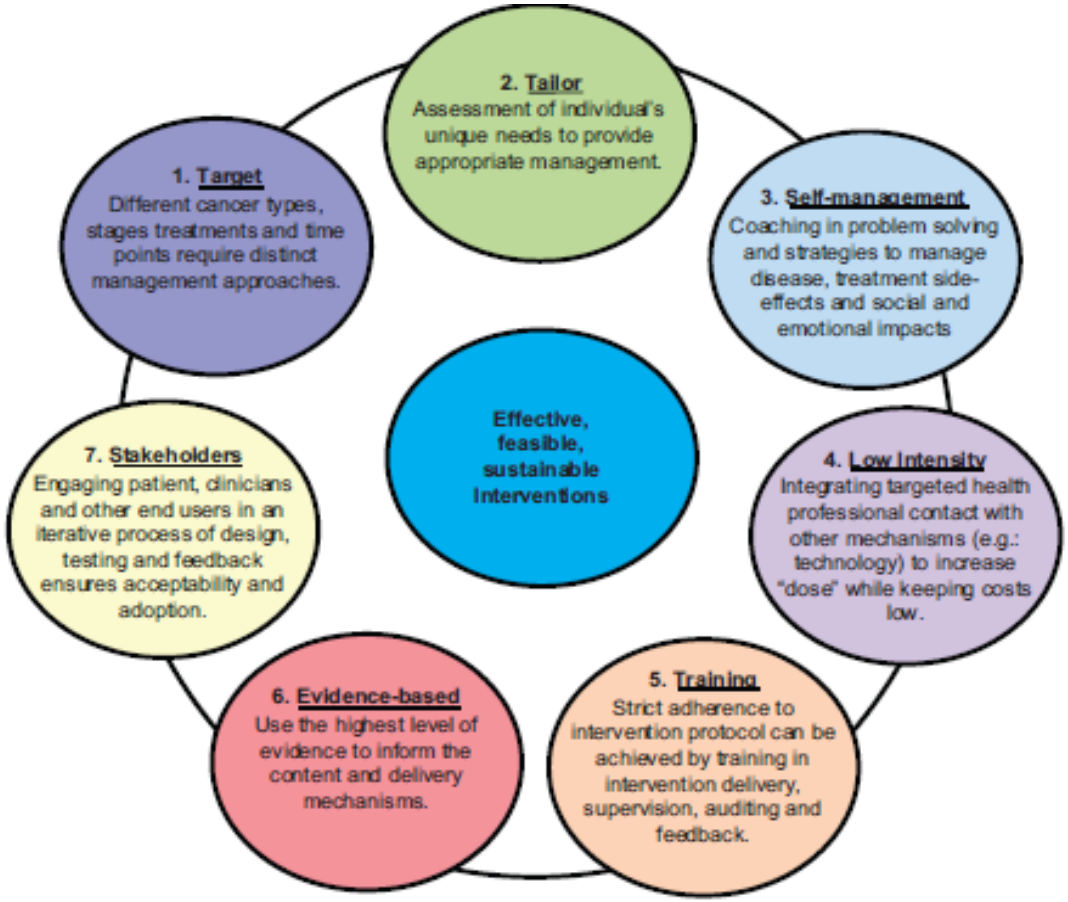


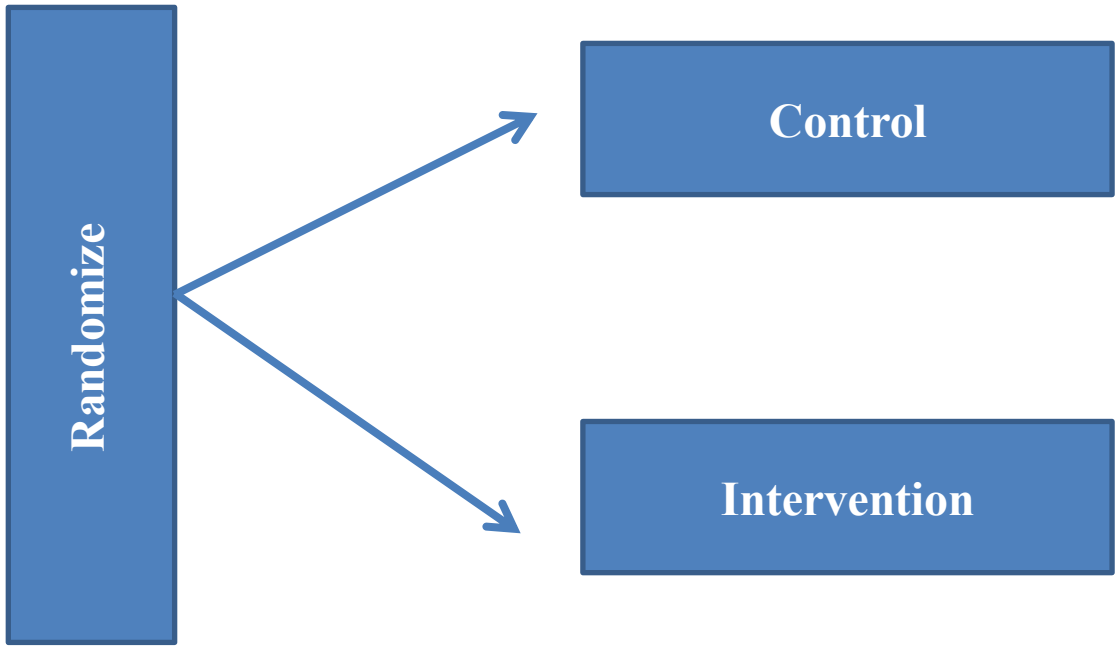
Figure 1. A framework for the development and delivery of psycho-educational and supportive care interventions.

Select study design

- A RCT is
  - a planned experiment designed to asses the efficacy of an intervention in human beings by comparing the intervention to a control condition
  - The allocation to intervention or control is determined purely by chance (randomization)
- RCTs are a subset of possible experimental designs

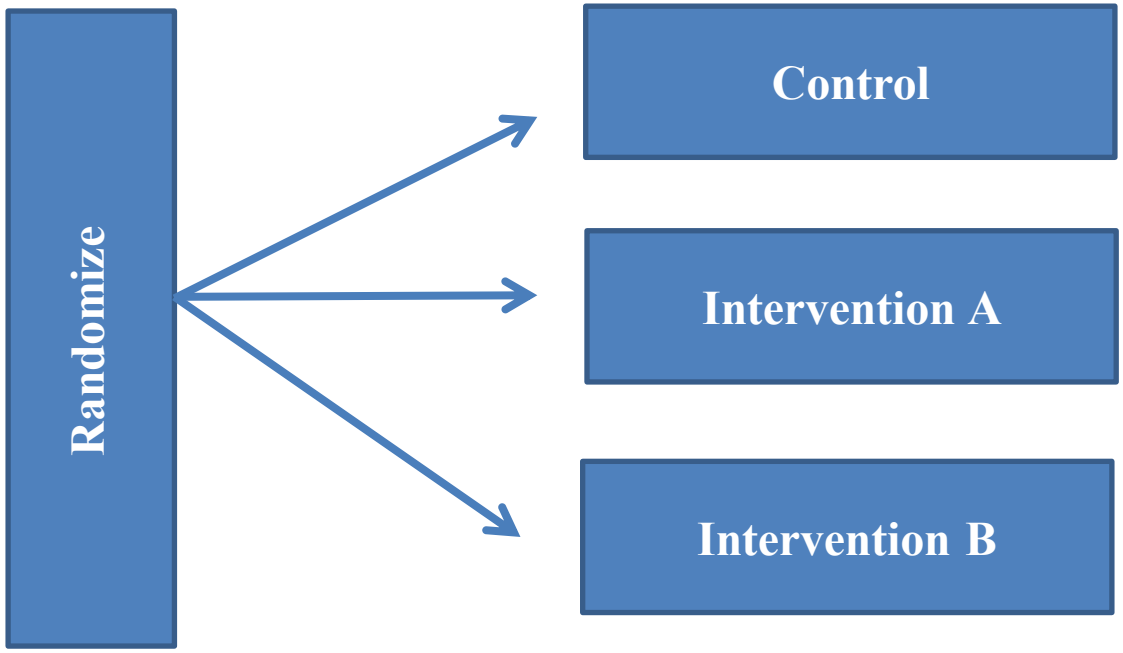
Select study design- intervention study

- Design options to lower placebo response
- Option 1. Parallel single stage design



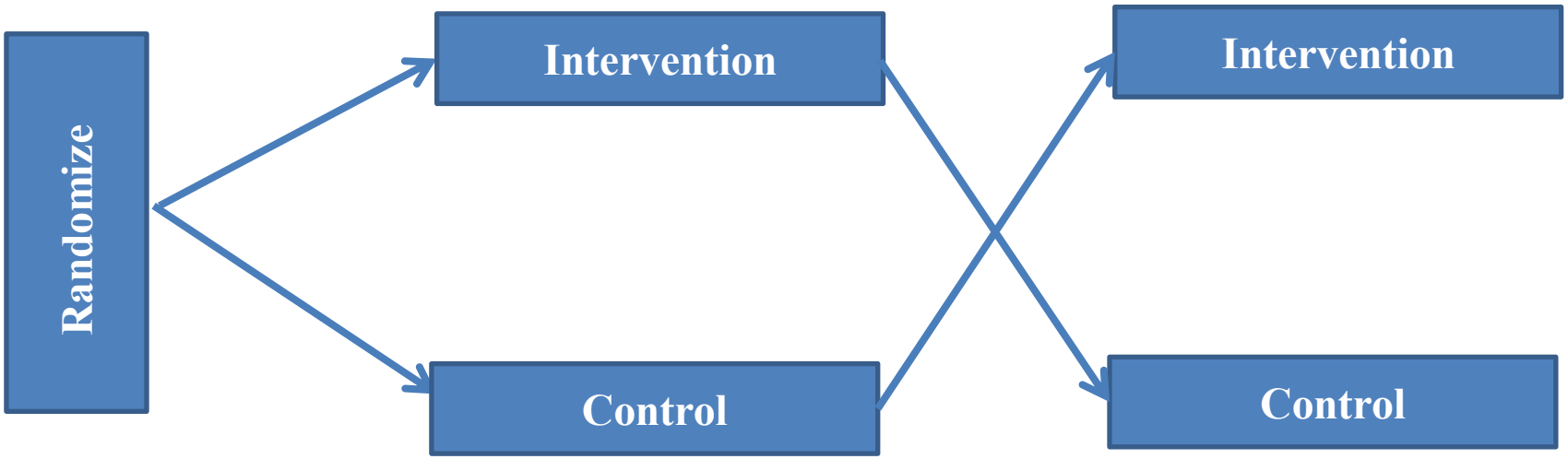
Select study design- intervention study

- Design options to lower placebo response
- Option 2. Multi-arm parallel



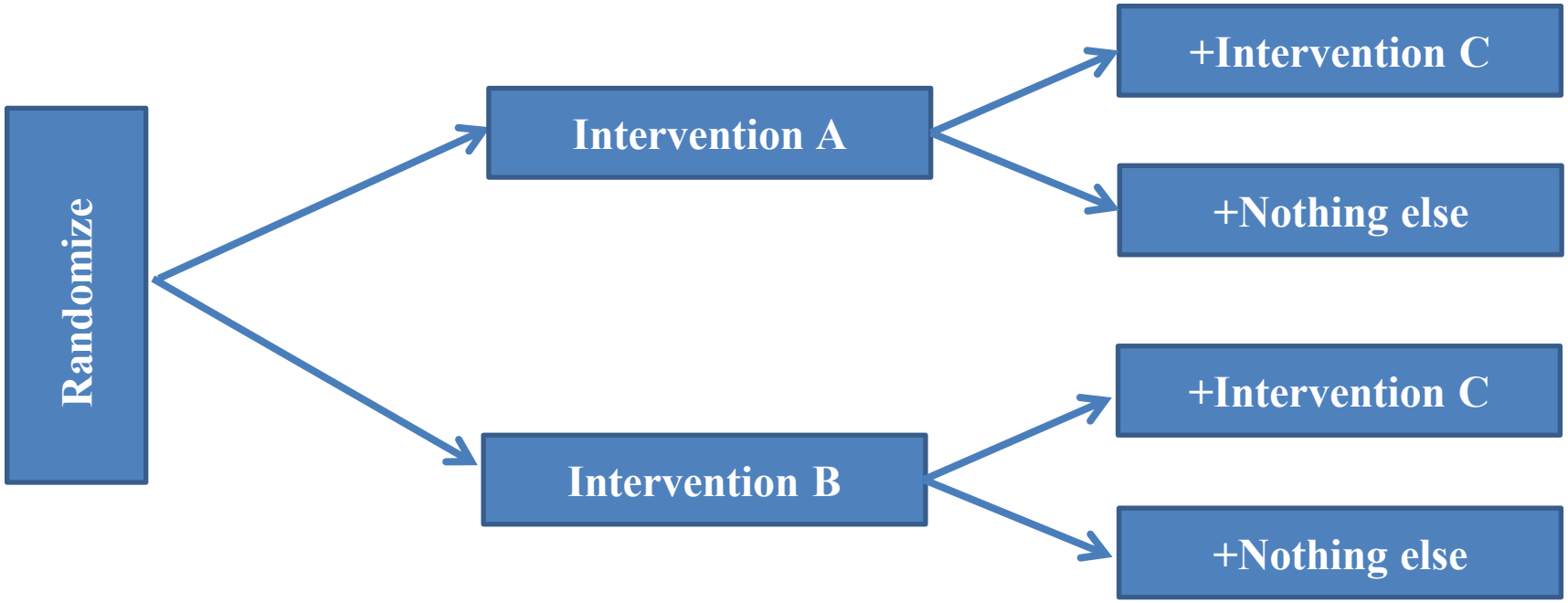
Select study design- intervention study

- Design options to comparison only subject to within-subject variability not between-subject variability with less patients .
- Option 3. Cross-Over Designs



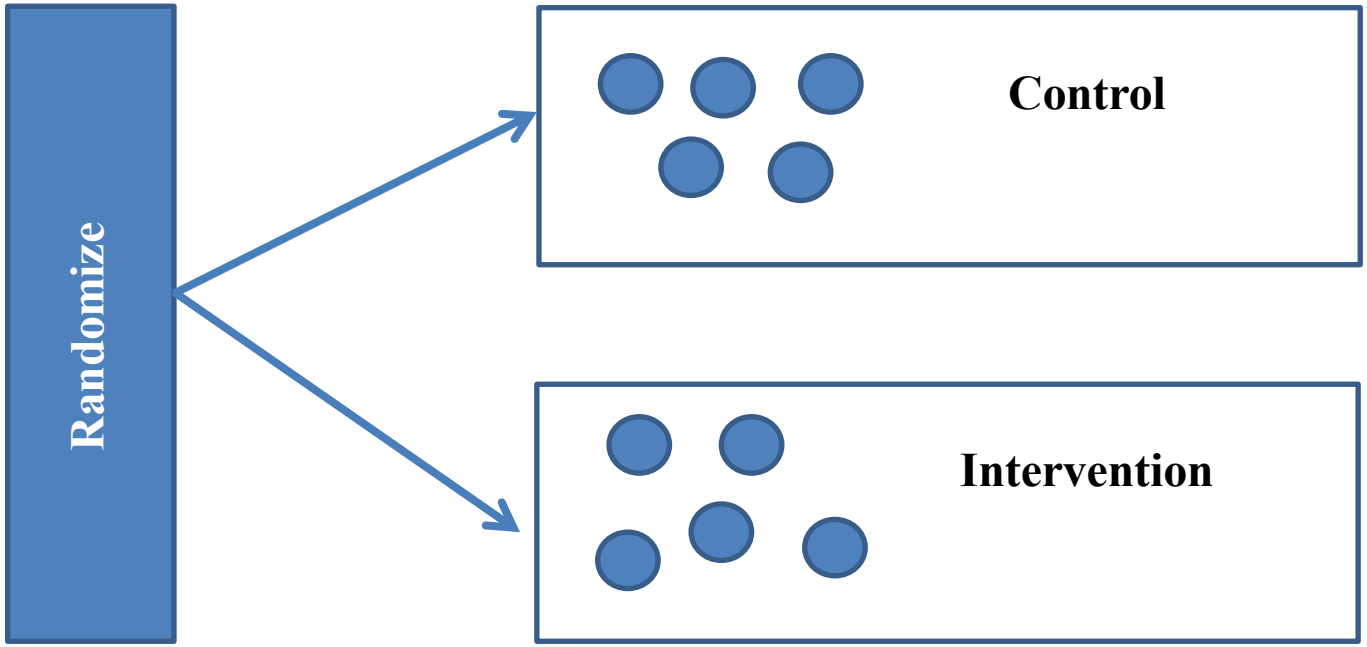
Select study design- intervention study

- Design options to permit the simultaneous test of two different hypotheses with less patients .
- Option 4. Factorial (Fractional)



Select study design- intervention study

- Design options
  - to compare to the nature of the intervention
  - to reduce self selection
  - cannot introduce the intervention in all units at once
- Option 5. Cluster randomized trial



Select study design- intervention study

- Design options to
  - fewer units needed (same as cross-over design)
  - cannot introduce the intervention in all units at once
  - Evaluate the community effectiveness
  - previously shown to be efficacious in an individually randomized trial or in a different setting; systematically evaluate new program
  - to study the effect of time on intervention effectiveness (i.e. seasonality, time since introduction)
- Option 6. Stepped Wedge Design

Select study design- intervention study

- Option 6. Stepped Wedge Design

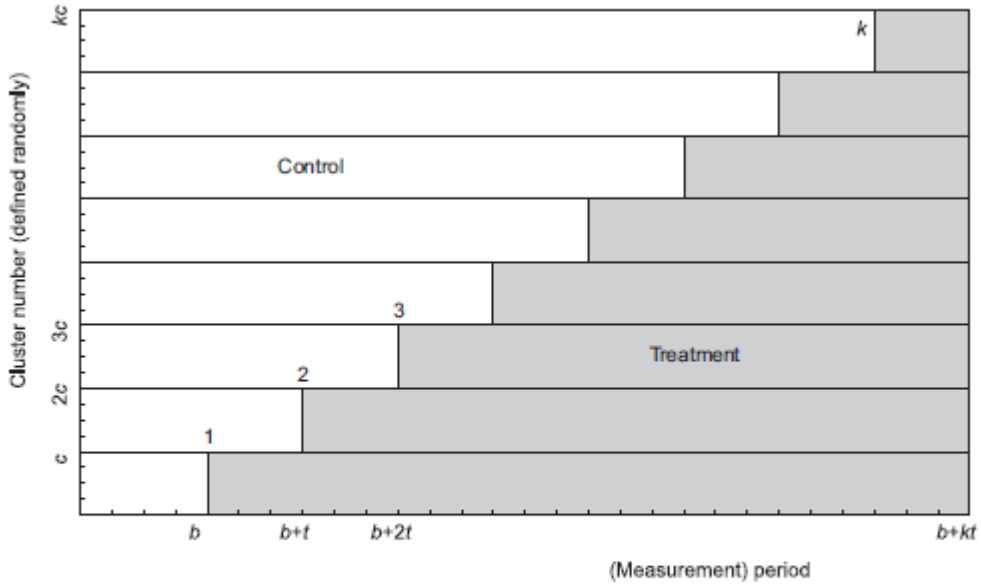


Fig. 1. Illustration of the stepped wedge design, where different (groups of) clusters switch from control to treatment at different time points.

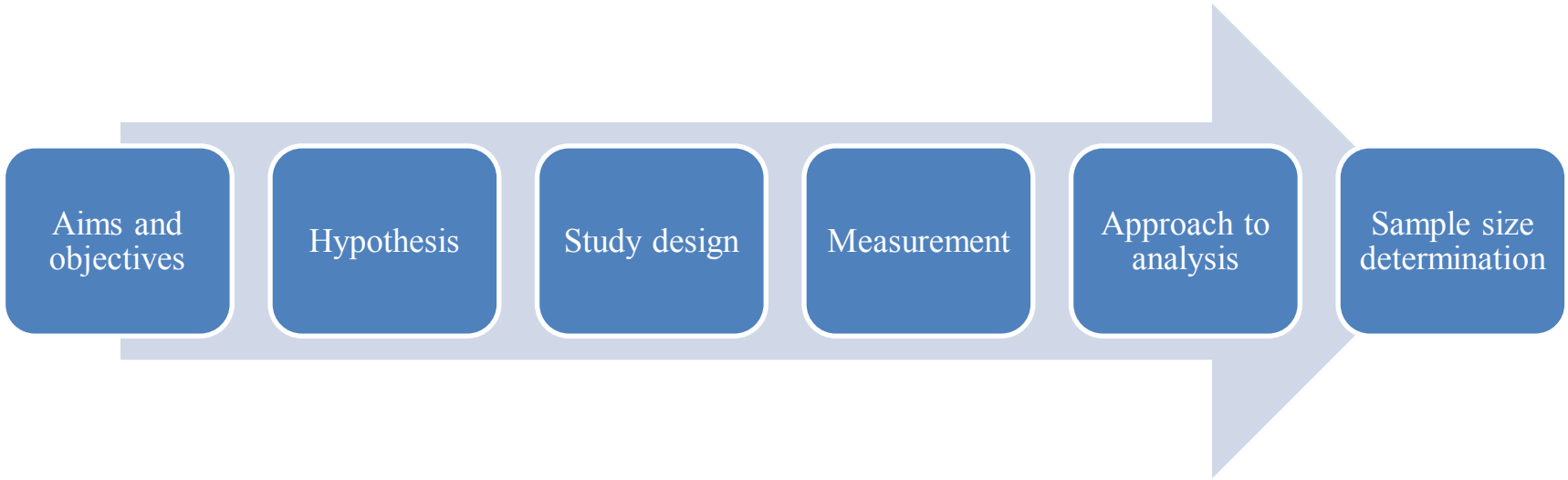
Woertman W. Stepped wedge designs could reduce the required sample size in cluster randomized trials. Journal of Clinical Epidemiology 66 (2013) 752e758

Study participants

- Consider feasibility
  - Identifying who may benefit from intervention (Ceiling and floor effects)
- Control group
  - Usual care
  - Placebo
  - Wait list control
  - Another intervention
  - Reduced intervention
  - Active control

Issues with sample size

- **Why dose sample size matter?**
  - Sample size can be too small to detect the effect of interest
  - Sample size can be unnecessarily large including more participants than is needed to detect the effect of interest
- **Sample size determination**



Sample size determination

- **Sample size calculation make use of the relationship among**
  - Sample size (N)
  - Significant criteria (alpha)
    - Alpha decided whether to accept that a finding from a sample is likely to be real or not, and usually it is 0.05
  - Statistical power (1-beta)
    - Beta represents the risk of mistakenly accepting the null hypothesis, and usually it is 0.20
  - Population effect size

Population effect size

- **The effect size is the discrepancy between**
  - The null hypothesis vs. alternate hypothesis $d = \frac{\bar{x}_1 - \bar{x}_2}{s}$
- **Cohen's d**
  - Cohen'd is the effect size index for the difference between two independent mean in the classical t-test
  - A d of 0.5 implies a half of a standard deviation difference between population means
    - hesitantly defined effect sizes as "small, $d = 0.2$," "medium, $d = 0.5$," and "large, $d = 0.8$",

Cohen's d

- **Do not use pilot study** effect sizes to answer this question
  - Studies worth performing are aborted
  - Studies not aborted are under-power
- Also not advisable to use sample size of a **previous study or trial** reporting statistically significant result

PERSPECTIVES

Caution Regarding the Use of Pilot Studies to Guide Power Calculations for Study Proposals

Helena Chmura Kraemer, PhD; Jim Mintz, PhD; Art Noda, MS; Jared Tinklenberg, MD; Jerome A. Yesavage, MD

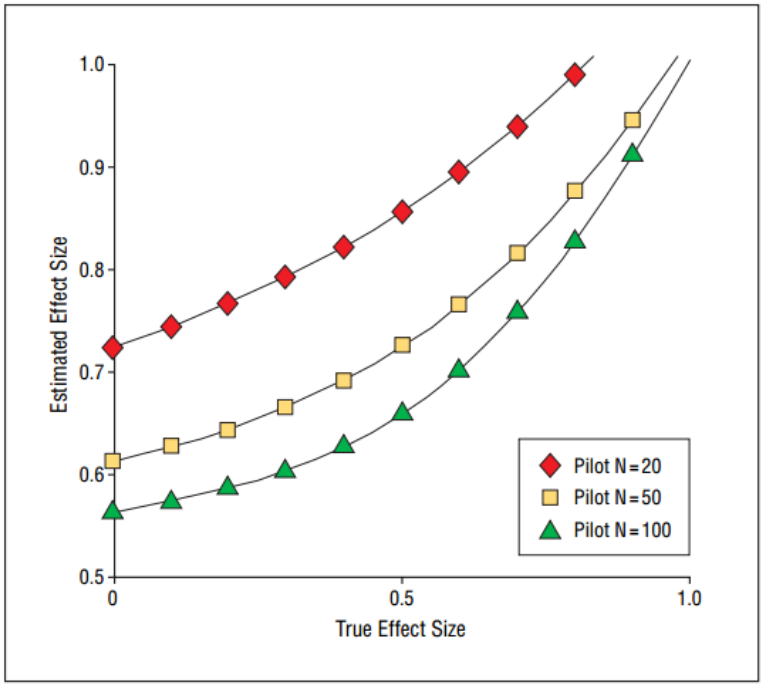


Figure 3. The estimated effect size if the study is not aborted, relative to the true effect size using pilot studies with sample sizes of 20, 50, and 100.

How to decide the effect size

- **Minimal important difference (MID) or minimal clinically important difference (MCID)**

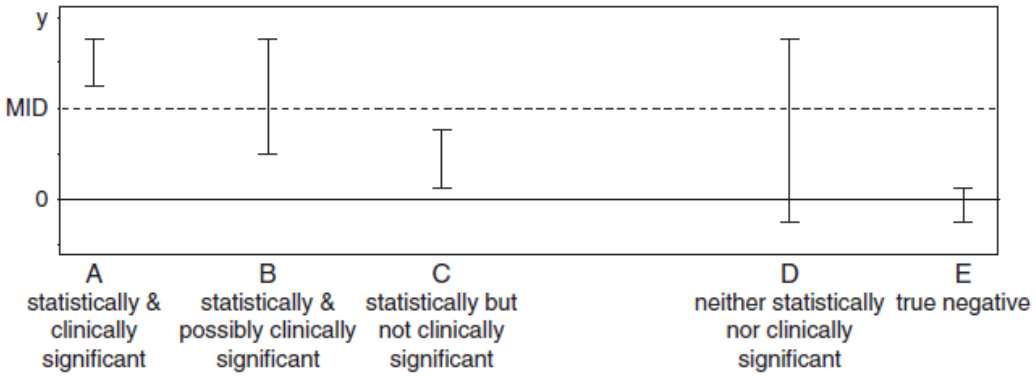


Figure 1. Interpretations of five cases of 95% confidence intervals, their relationship to the null values (0) and the minimal important different (MID).

King MT. A point of minimal important difference (MID): a critique of terminology and methods Expert Rev. Pharmacoeconomics Outcomes Res. 11(2), 171–184 (2011)

How to decide the effect size

- **Half a standard deviation**

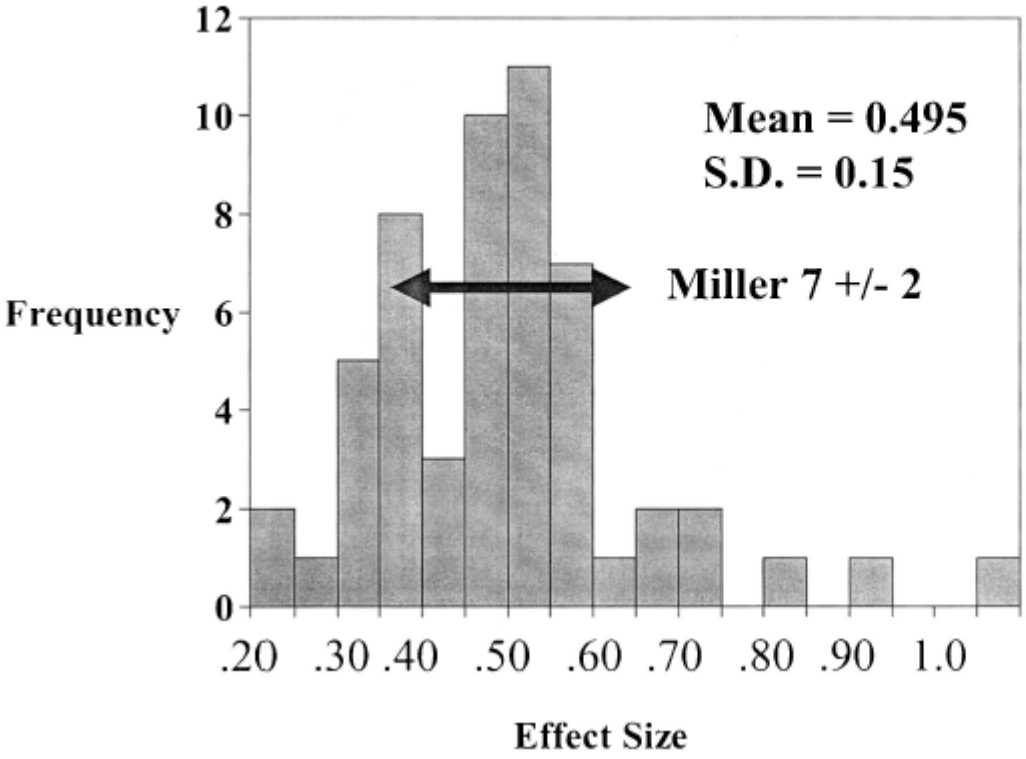


FIG. 1. Distribution of effect sizes computed from 56 estimates of the minimal difference derived from 33 studies.

Norman GR. Interpretation of Changes in Health-related Quality of Life The Remarkable Universality of Half a Standard Deviation. MEDICAL CARE Volume 41, Number 5, pp 582–592

How to decide the effect size

- **10% of the instrument range**

Interpreting Clinically Significant Changes in Patient-Reported Outcomes

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Donald A. Redelmeier, MD[2]

[1] Department of Radiation Oncology, Princess Margaret Hospital and University of Toronto, Toronto, Ontario, Canada.

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BACKGROUND. The goal of this study was to determine what magnitude of change in a patient-reported outcome score is clinically meaningful, so a clinicians' guide may be provided for estimating the minimal important difference (MID) when empiric estimates are not available.

METHODS. Consecutive laryngeal cancer patients (n = 98) rated their quality of life (QOL) relative to other patients. These comparisons were contrasted with arithmetic differences in scores on the Functional Assessment of Cancer Therapy-Head and Neck (FACT-H&N) scale, Functional Assessment of Cancer Therapy-General (FACT-G) scale, 2 utility measures (the time tradeoff [TTO] and Daily Active Time Exchange [DATE]), and performance status (Karnofsky) scores.

RESULTS. The FACT-H&N score needed to differ by 4% for average patients to rate themselves as "a little bit better" relative to other patients (95% CI, 1%–8%) and by 9% to rate themselves as "a little bit worse" relative to others (95% CI, 4%–13%). The corresponding values for other measures were FACT-G 4% (1%–7%) and 8% (95% CI, 5%–11%); TTO 5% (95% CI, 0%–11%) and 6% (95% CI, 0%–10%); DATE [illegible] CI, 1%–6%) a
ference (MID
CONCLUSIONS benchmark
sensitive to f
This simple
Cancer 2007;

ference (MID) was about 5% to 10% of the instrument range.

CONCLUSIONS. One rule of thumb for interpreting a difference in QOL scores is a benchmark of about 10% of the instrument range. Patients appear to be more sensitive to favorable differences, so an improvement of 5% may be meaningful. This simple benchmark may be useful as a rough guide to meaningful change.

***Cancer* 2007;110:196–202.** © *2007 American Cancer Society.*

Presented in part at the American Society of

Ringash J. Norman GR. Interpreting Clinically Significant Changes in Patient-Reported Outcomes. Cancer 2007;110:196–202.

How to decide the effect size

- **Binary outcome variable— proportions**
  - This approach reduces power (~30% for dichotomizing), loses information, eats up degrees of freedom.

Table

Table 1| **Sample sizes for various combinations of relative risk reduction and base rate***

	Relative risk reduction		
Base rate	**0.08**	**0.16**	**0.25**
0.01	247 500	61875	25300
0.02	122500	30625	12550
0.05	47500	11875	4 865
0.1	22500	5625	2 300
0.2	10000	2 500	1025
0.5	2 500	625	255

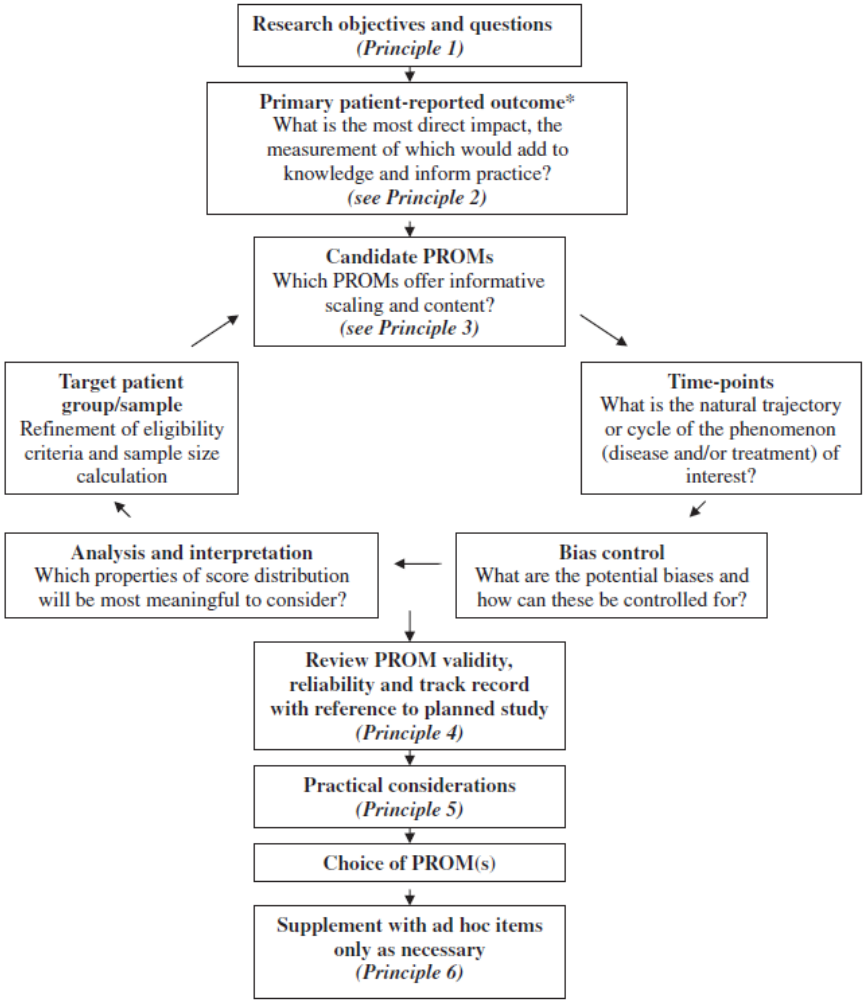
*Sample size based on the approximate formula $n=16\times(BR(1-BR))/ARR^2$, where BR=base rate and ARR=absolute risk reduction. Sample sizes are rounded to the nearest 5 or 0.

Norman GR. Sample size calculations: should the emperor's clothes be off the peg or made to measure?.

Choice of appropriate assessment measures

- What are the specific outcome constructs that **will be <u>influenced by the intervention</u>**?
- What is the **<u>population</u>** of interest
- What is the **<u>time frame</u>** of interest

Measurements



* The same process should be repeated for each secondary and tertiary patient-reported outcome. In these cases, the question is 'what is the next most important impact, the measurement of which would add to knowledge and inform practice?'

Fig. 1 – Algorithm for choosing patient-reported outcome measures (PROMs).

Luckett T. Choosing patient-reported outcome measures for cancer clinical research . Practical principles and an algorithm to assist non-specialist researchers. european journal of cancer 4 6 (2 0 1 0) 3 1 4 9 .3 1 5 7

review

Annals of Oncology 22: 2179–2190, 2011
doi:10.1093/annonc/mdq721
Published online 21 February 2011

Choosing between the EORTC QLQ-C30 and FACT-G for measuring health-related quality of life in cancer clinical research: issues, evidence and recommendations

T. Luckett[1,2*], M. T. King[1], P. N. Butow[1,3], M. Oguchi[1,3], N. Rankin[1,4], M. A. Price[1,3], N. A. Hackl[5] & G. Heading[5,6]

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Received 15 June 2010; revised 31 August 2010; accepted 15 November 2010

Background: This review aims to assist cancer clinical researchers in choosing between the two most widely used measures of cancer-specific health-related quality of life: the European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire Core 30 and Functional Assessment of Cancer Therapy—General (FACT-G).
Materials and methods: Information on QLQ-C30 and FACT-G content, scale structure, accessibility and availability was collated from websites and manuals. A systematic review was undertaken to identify all articles reporting on psychometric properties and information to assist interpretability. Evidence for reliability, validity and responsiveness was rated using a standardised checklist. Instrument properties were compared and contrasted to inform recommendations.
Results: Psychometric evidence does not recommend one questionnaire over the other in general. However, there are important differences between the scale structure, social domains and tone that inform choice for any particular study.
Conclusions: Where research objectives are concerned with the impact of a specific tumour type, treatment or symptom, choice should be guided by the availability, content, scale structure and psychometric properties of relevant European Organisation for the Research and Treatment of Cancer versus Functional Assessment of Chronic Illness Therapy modules. Because the FACT-G combines symptoms and concerns within each scale, individual items should always be reviewed within the context of specific research objectives. Where these issues are indecisive, researchers are encouraged to use an algorithm at the end of the current article.
Key words: psychometrics, quality of life, questionnaires

Choice of appropriate **assessment measures**

EORTC-C30, social functioning

*** 지난 한 주를 기준으로 답변하여 주십시오.**

		전혀 아니다	약간 그렇다	꽤 그렇다	매우 그렇다
6	일을 하거나 기타 일상생활을 영위하는데 한계를 느낀 적이 있습니까?	1	2	3	4
7	취미생활이나 여가활동을 하는데 있어 한계를 느낀 적이 있습니까?	1	2	3	4

Weak to moderate correlation, r=0.10-0.50

FACT-G, social well-being

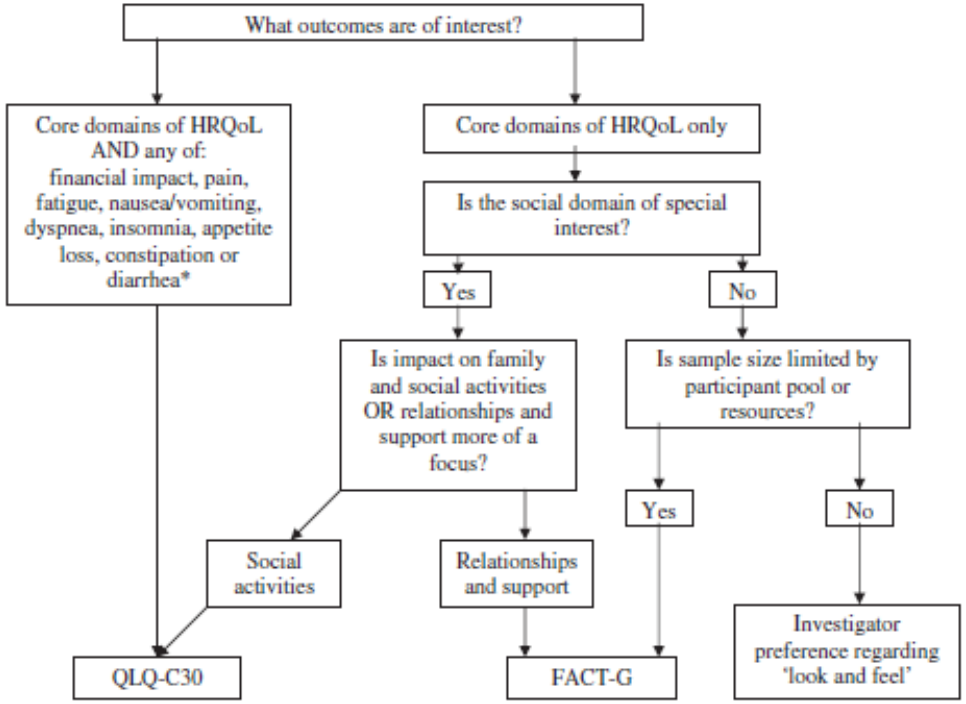
	전혀 그렇지 않다	조금 그렇다	보통이다	다소 그렇다	매우 그렇다
사회/가족 영역					
1. 친구들과 가까워지는 듯한 느낌이 든다.	0	1	2	3	4
2. 정서적으로 가족들의 따뜻한 보살핌을 받는다.	0	1	2	3	4
3. 친구들로부터 도움을 받는다.	0	1	2	3	4
4. 내 가족들은 내 병을 받아들였다.	0	1	2	3	4
5. 내 병에 대한 가족들의 대화에 만족한다.	0	1	2	3	4
6. 배우자와 가깝게 느낀다	0	1	2	3	4

Luckett T. Choosing between the EORTC QLQ-C30 and FACT-G for measuring health-related quality of life in cancer clinical research: issues, evidence and recommendations. Annals of Oncology 22: 2179–2190, 2011

Choice of appropriate **assessment measures**

Annals of Oncology

review



*Where cognitive functioning is an outcome of interest, researchers are encouraged to seek a dedicated questionnaire rather than rely on the scale included in the QLQ-C30.

Figure 1. Decision tree for choosing between the Quality of Life Questionnaire Core 30 (QLQ-C30) and Functional Assessment of Cancer Therapy—General (FACT-G) when availability and psychometric properties of modules and/or translated versions and item-by-item content of FACT-G items are not deciding factors. HRQoL, health-related quality of life.

Luckett T. Choosing between the EORTC QLQ-C30 and FACT-G for measuring health-related quality of life in cancer clinical research: issues, evidence and recommendations. Annals of Oncology 22: 2179–2190, 2011

Psycho-Oncology
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Scientific rigour in psycho-oncology trials: why and how to avoid common statistical errors

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Revised: 15 January 2012
Accepted: 16 January 2012

Abstract

Objective: **It is well documented that statistical and methodological flaws are common in much of the health research literature, including psycho-oncology. These can have far-reaching effects, including the publishing of misleading results; the wasting of time, effort, and financial resources; exposure of patients to the potential harms of research and decreased confidence in science and researchers by the public.**

Methods: **Several of the most common statistical errors and methodological pitfalls that occur in the field of psycho-oncology are discussed, including those that occur at the design, analysis, reporting and conclusion stages.**

Results: **Fourteen topics are briefly discussed, explaining why there is a problem and how to avoid it. These include proper approaches to power, clustering, missing data, categorization of continuous variables, subgroup analyses, multiple comparisons, statistical interactions, confidence intervals and correct interpretation of *p*-values. Extensive referencing points the reader to more in-depth explanations.**

Conclusions: **To increase the scientific rigour in psycho-oncology, researchers should involve a biostatistician from the beginning of the study and should commit to continuing education on best practices in the fields of statistics and reporting.**

Keywords: cancer; oncology; design; analysis; reporting; quality control; pitfalls

Annals of Internal Medicine | ACADEMIA AND CLINIC

Extending the CONSORT Statement to Randomized Trials of Nonpharmacologic Treatment: Explanation and Elaboration

Isabelle Boutron, MD, PhD; David Moher, PhD; Douglas G. Altman, DSc; Kenneth F. Schulz, PhD, MBA; and Philippe Ravaud, MD, PhD, for the CONSORT Group

Adequate reporting of ra
essary to allow accurate
cability of the results. Th
Reporting Trials) Stateme
is intended to address th
RCTs. However, some s
pharmacologic treatments
tions, devices, rehabilitati
vention) are not specifical
Furthermore, considerabl
nonpharmacologic trials
CONSORT group develo
ment for trials assessing n
meeting of 33 experts w
2006, to develop an ex

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

SPECIAL COMMUNICATION

Reporting of Patient-Reported Outcomes in Randomized Trials

The CONSORT PRO Extension

Melanie Calvert, PhD
Jane Blazeby, MD
Douglas G. Altman, DSc
Dennis A. Revicki, PhD
David Moher, PhD
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for the CONSORT PRO Group

The CONSORT (Consolidated Standards of Reporting Trials) Statement aims to improve the reporting of randomized controlled trials (RCTs); however, it lacks guidance on the reporting of patient-reported outcomes (PROs), which are often inadequately reported in trials, thus limiting the value of these data. In this article, we describe the development of the CONSORT PRO extension based on the methodological framework for guideline development proposed by the Enhancing the Quality and Transparency of Health Research (EQUATOR) Network. Five CONSORT PRO checklist items are recommended for RCTs in which PROs are primary or important secondary end points. These recommendations urge that the PROs be identified as a primary or secondary outcome in the abstract, that a description of the hypothesis of the PROs and relevant domains be provided (ie, if a multidimensional PRO tool has been used), that evidence of the PRO instrument's validity and reliability be provided or cited, that the statistical approaches for dealing with missing data be explicitly stated, and that PRO–specific limitations of study findings and generalizability of results to other populations and clinical practice be discussed. Examples and an updated CONSORT flow diagram with PRO items are provided. It is recommended that the CONSORT

THE CONSORT (CONSOLIdated Standards of Reporting Trials) Statement, first published in 1996 and most recently revised in 2010,[1,2] provides evidence-based recommendations to improve the completeness of reporting of randomized controlled trials (RCTs). The statement focuses on parallel-group trials, but a number of extensions for reporting other trial de-

Statistical analysis plan

- **To prepare an adequate analysis plan, you will need to decide the following**
  - Intention to treat and/or per-protocol analysis
  - Statistical procedures to be used for primary and additional analyses (and any assumptions about missing data these may entail)
  - Composite endpoints or summary measures consistent with study objectives
  - Multiplicity adjustment
  - Expected rate and handling of missing forms (and any sensitivity analysis)

STATISTICS IN MEDICINE, VOL. 13, 1715–1726 (1994)

TESTING FOR BASELINE BALANCE IN CLINICAL TRIALS*

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SUMMARY

Once the data from a clinical trial are available for analysis it is common practice to carry out 'tests of baseline homogeneity' on prognostic covariates before proceeding to analyse the effects of treatment on outcome variables. It is argued that this practice is philosophically unsound, of no practical value and potentially misleading. Instead it is recommended that prognostic variables be identified in the trial-plan and fitted in an analysis of covariance regardless of their baseline distribution (statistical significance).

Bland and Altman *Trials* 2011, **12**:264
http://www.trialsjournal.com/content/12/1/264

TRIALS

METHODOLOGY Open Access

Comparisons against baseline within randomised groups are often used and can be highly misleading

J Martin Bland[1*] and Douglas G Altman[2]

Abstract

Background: In randomised trials, rather than comparing randomised groups directly some researchers carry out a significance test comparing a baseline with a final measurement separately in each group.

Methods: We give several examples where this has been done. We use simulation to demonstrate that the procedure is invalid and also show this algebraically.

Results: This approach is biased and invalid, producing conclusions which are, potentially, highly misleading. The actual alpha level of this procedure can be as high as 0.50 for two groups and 0.75 for three.

Conclusions: Randomised groups should be compared directly by two-sample methods and separate tests against baseline are highly misleading.

Keywords: Baseline, significance, comparison, within-group, type I error, alpha, ageing

Sources of multiple testing

- Multiple outcomes
- Multiple predictors
- Subgroup analyses
- Multiple definitions for the exposures and outcomes
- Multiple time points for the outcome
- Multiple looks at the data

Principled handling of missing data

- **1. Replacing missing observations with a single value**
  - such as the mean or the last observation,
  - but, it can both increase the type I error rate by artificially reducing the variance in the data and cause biased estimation
- **2. just ignore missingness by performing a complete case analysis,**
  - but it can result in bias if the reason for missingness is related to the outcome.

Fairclough DF. Design and Analysis of Quality of Life Studies in Clinical trials. 2nd ed: Chapman & Hall/CRC: Boca Raton, Fl, 2010.

Principled handling of missing data

- **3. The use of maximum likelihood methods such as mixed models**
  - are best practices for the analysis of longitudinal data where some of the outcomes are not observed (if less than 10%)
- **4. Sensitivity analysis**
- **5. Missing imputation**

Carpenter J, Kenward M. Missing Data in Randomised Controlled Trials – A ractical Guide. National Institute for Health Research: In. Birmingham, 2008.

Reporting missing data

- Missing data rates, by treatment arm, should be reported, particularly in longitudinal studies.
  - the CONSORT statement's flowchart can be a good means for doing this
  - the possible effects of attrition should be discussed as well, with sensitivity analyses performed and discussed to demonstrate the robustness of the results to missing data assumptions

Thank you

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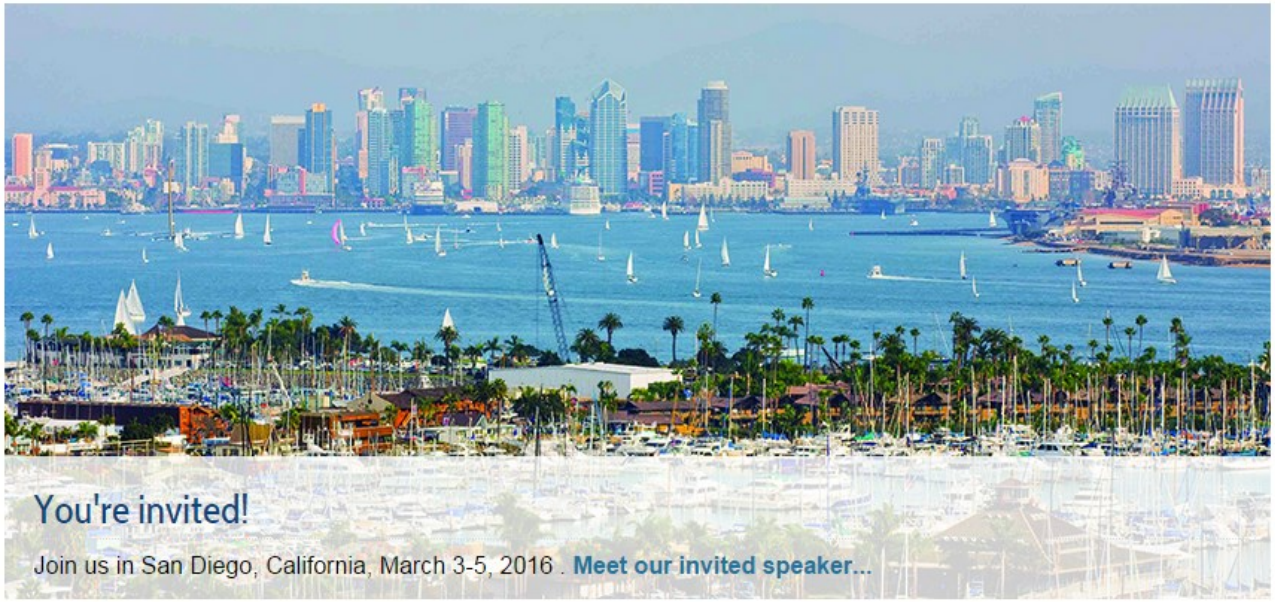
October 5, 2015
Abstract Submission Deadline

March 3, 2016
Preconference Workshops, Opening Reception and Awards Ceremony

March 4-5, 2016
Conference Sessions, Exhibits and Posters



Psychosocial Care for All: Achieving Equity in Psychosocial Oncology Across Ethnic, Racial and Cultural Minorities

The APOS 13th Annual Conference will feature one day of preconference workshops, followed by two-days of educational conference sessions. The conference will be held at the Sheraton San Diego Hotel and Marina.