FIRST NATIONAL WORKSHOP ON EVIDENCE-BASED DENTISTRY

10-11, March 2001

CENTRE FOR EVIDENCE-BASED DENTISTRY AND INFORMATICS
COLLEGE OF DENTAL SCIENCES
KARNATAKA, DAVANGERE 577 004, INDIA
URL: http://www.cods.net/cebd/

Centre for
Evidence-Based Dentistry & Informatics
College of Dental Sciences, Davangere
extends an invitation to the

Inaugural Ceremony

OF THE FIRST
NATIONAL WORKSHOP ON
EVIDENCE-BASED DENTISTRY

Chief Guest
Dr. S. Chandrashekar Shetty
Hon'ble Vice-Chancellor, RGUHS

Guest of Honour
Padmashree Dr. R. K. Bali
President, DCI

esided over by
ıri S. Shivashankarappa
ɔn. Secretary, BEA

Guest of Honour
Shri I. P. Vishwaradhya
Chairman, CODS

Special Invitees

: Derek Richards
rector, CEBD, Oxford

Dr. Asbjorn Jokstad
Member, FDI Commission
Norway

Dr. T. Samraj
Prof & Head, Dept. of Dental Surgery
Christian Medical College, Vellore

Saturday, 10th March 2001, 11.00 am
Seminar Hall, College of Dental Sciences

. V. V. Subba Reddy
airman, CEBD-i

Dr. Anmol S. Kalha
Chief Convener

PROGRAMME

DAY ONE: 10 March, 2001

0800 hrs	Breakfast and Registration
0900 hrs	**Orientation to EBD**
	The CODS-EBD Staff
1000 hrs	**EBD: Glossary of terms**
	Dr. Sukhdeep Singh
1030 hrs	Tea
1100 hrs	Inaugural Function
1230 hrs	**Why EBD?**
	Dr. A. S. Kalha
1300 hrs	Lunch
1400 hrs	**Introduction to EBD**
	Dr. Derek Richards
1430 hrs	**Asking the right question**
	Small group exercise
1515 hrs	**Levels and sources of evidence**
	Small group exercise
1615 hrs	Tea
1630 hrs	**Demystifying Computers & Internet**
	Dr R. V. Subramanyam
1645 hrs	**Searching for evidence**
	Small group exercise
1800 hrs	TEA
1815 hrs	Hands-on session continues
2000 hrs	BANQUET

DAY TWO: 11 March, 2001

0800 hrs	BREAKFAST
0900 hrs	**Are you scared of numbers?**
	Dr. Shailesh M. Lele
0930 hrs	**Introduction to Critical Appraisal**
1035 hrs	**Appraising Randomised Clinical Trials (RCTs)** Hands-on course
1130 hrs	TEA
1145 hrs	**Feedback and Plenary on RCTs** — ASBJORN JOKSTAD
1300 hrs	LUNCH
1400 hrs	**Introduction to Systematic Reviews**
1500 hrs	Small group exercise
1545 hrs	**Feedback and Plenary on Systematic Reviews**
1630 hrs	Valedictory function

Randomised Controlled Trials and Oral Implants

Asbjørn Jokstad
Dental Faculty
University of Oslo

Prosthetic Dentistry

The discipline of dentistry concerned with

the consequences of congenital absence or acquired loss of oral tissues

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The discipline of dentistry concerned with the consequences of congenital absence or acquired loss of oral tissues

on appearance, stomatognathic function, comfort, and local and general health of the patient

Prosthetic Dentistry

The discipline of dentistry concerned with the consequences of congenital absence or acquired loss of oral tissues on appearance, stomatognathic function, comfort, and local and general health of the patient,

and with the methods for, and assessment if more good than harm is done by, inserting artificial devices made from alloplastic materials to change these conditions*.

*Jokstad A, Ørstavik J, Ramstad T. A Definition of Prosthetic Dentistry. Int J Prosthodont 1998; 11:295-301.














Objectives

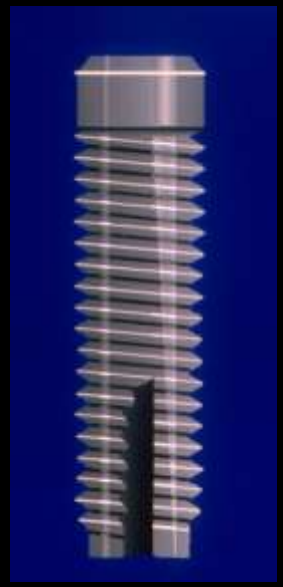
1. To test the null hypothesis of no difference in the success, function and patient satisfaction between conventional prostheses and oral implants against the alternative hypothesis of a difference.

Date of most recent	09 February 2000

Oral Implants

Dentists have to choose from more than 1,300 implants*.

These vary in form, material, dimension, surface properties and interface geometry.



*Binon PP. Implants and components: entering the new millennium. Int J Oral Maxillofac Implants 2000;15:76-94

Objectives

1. To test the null hypothesis of no difference in the success, function and patient satisfaction between conventional prostheses and oral implants against the alternative hypothesis of a difference.

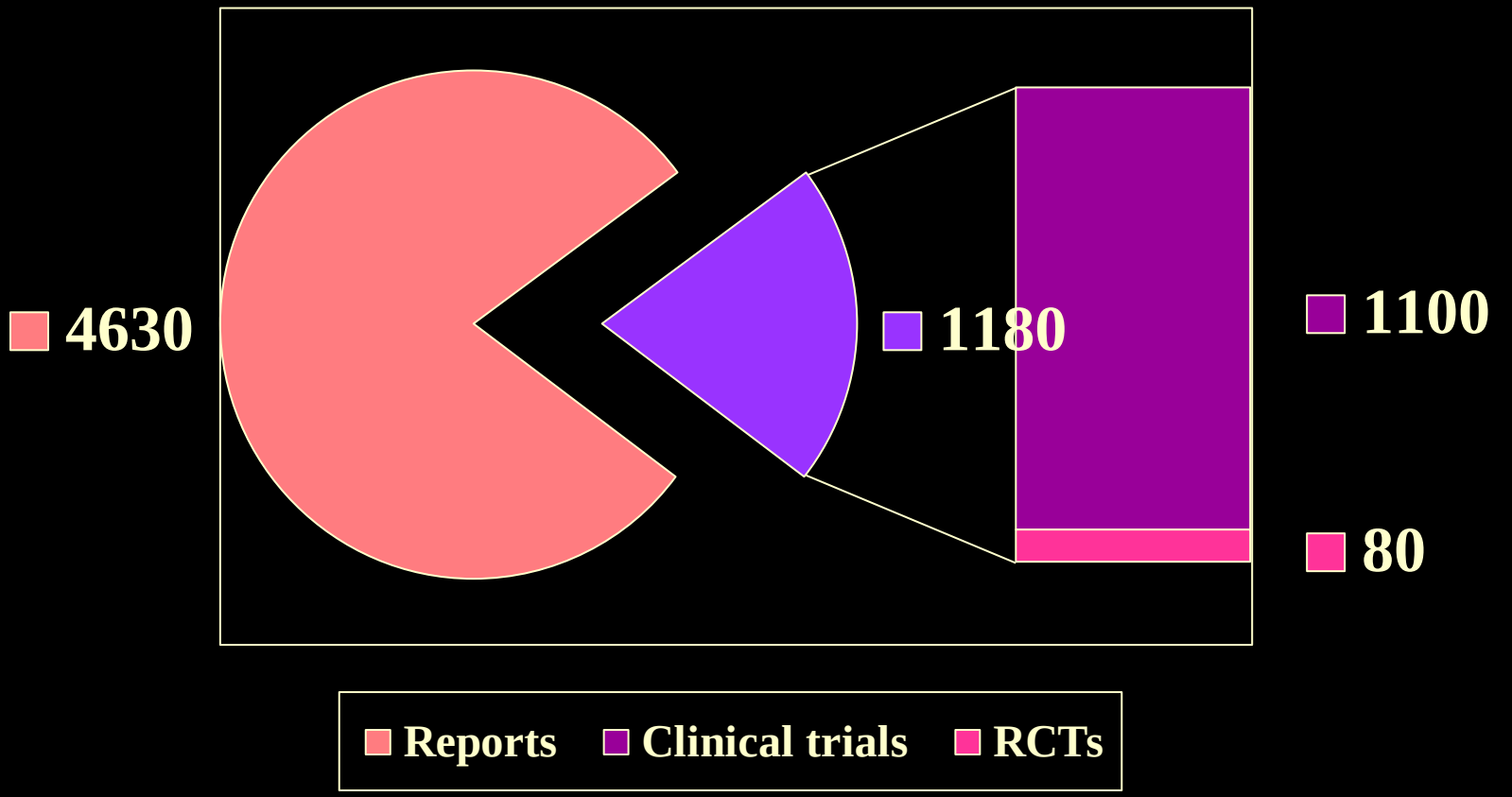
2. To test the null hypothesis of no difference in the long term success, morbidity, function and patient satisfaction between different oral implant characteristics and techniques against the alternative hypothesis of a difference.

Date of most recent	09 February 2000

Method of a review- Search for papers

1. Search of the Cochrane Oral Health Group specialist register, using key words (e.g. prosthesis, bridge, implant*). Based on handsearch of journals .
2. Search for RCT trials in Medline
3. Search of the bibliographies of identified RCTs, reviews and personal references
4. Letters to first named authors of identified RCTs for further information about trials and attempts to identify unpublished studies

Randomised Controlled Trials in Oral Implant research



Method of a review- Initial data synthesis

1. Two reviewers work independently, and in duplicate.
2. The relevance of each potentially interesting article appraised in a non-blinded fashion with regard to the types of intervention.
3. Recordings of article ownership, affiliation, year of publication and journal.
4. Identification of funding source (commercial, independent or unclear) clinical setting (university, non-university, unclear) study design (parallel, split-mouth or cross-over) and sample size.

Method of a review- Quality assessment

5. Quality assessment of RCTs trials with sample sizes:
   - ≥ 10 for parallel trials
   - ≥ 5 for split-mouth and cross-over studies

A sensitivity analysis conducted if appropriate.

Method of a review- Quality assessment

A) Was a sample size calculation undertaken?

B) Randomization and allocation concealment method

C) Were inclusion/exclusion criteria clearly defined?

D) Was reason for withdrawal specified by study group?

E) Were the control and treatment groups comparable at entry for important prognostic factors?

F) Was there any attempt at blinding (for example, independent assessor)?

G) Was the statistical analysis appropriate?

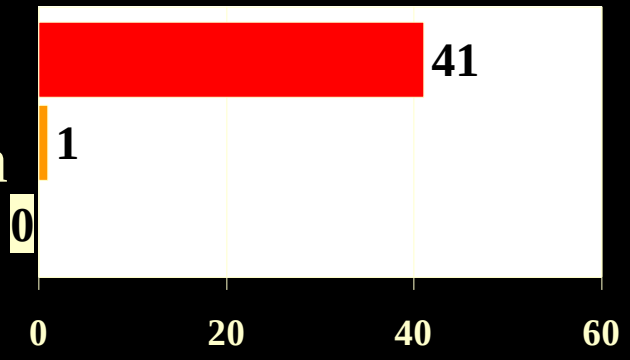
Method of a review- Quality assessment

A) Was a sample size calculation undertaken?

0 No/not mentioned

1 Yes, but not confirmed by calculation

2 Yes, confirmed



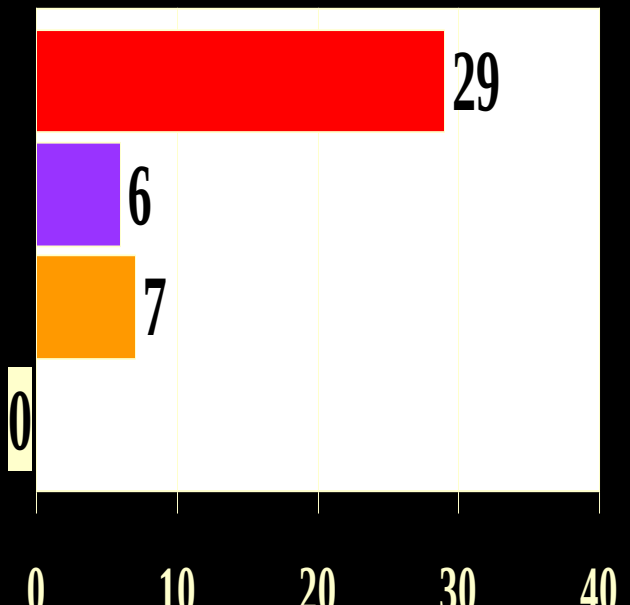
B) Randomization and allocation concealment method

0 Not described

1 Clearly inadequate - transparent before assignment

2 Possibly adequate-sealed envelopes

3 Clearly adequate- centralized randomization and third party contact for group code



Method of a review- Quality assessment

A) Was a sample size calculation undertaken?

B) Randomization and allocation concealment method

C) Were inclusion/exclusion criteria clearly defined?

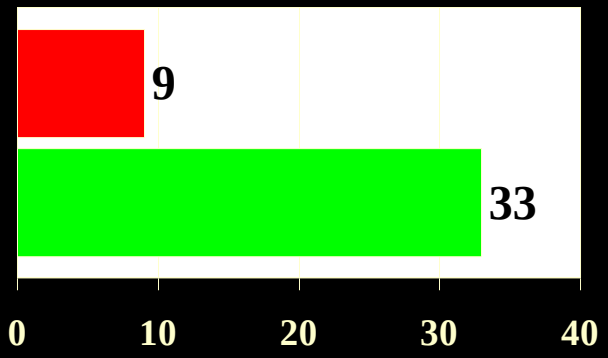
0 No

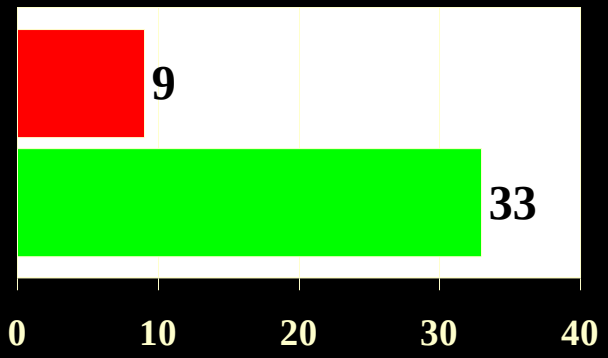
1 Yes

D) Was reason for withdrawal specified by study group?

0 No/not mentioned

1 Yes, or not applicable as no withdrawals





Method of a review- Quality assessment

A) Was a sample size calculation undertaken?

B) Randomization and allocation concealment method

C) Were inclusion/exclusion criteria clearly defined?

D) Was reason for withdrawal specified by study group?

E) Were the control and treatment groups comparable at entry for important prognostic factors?

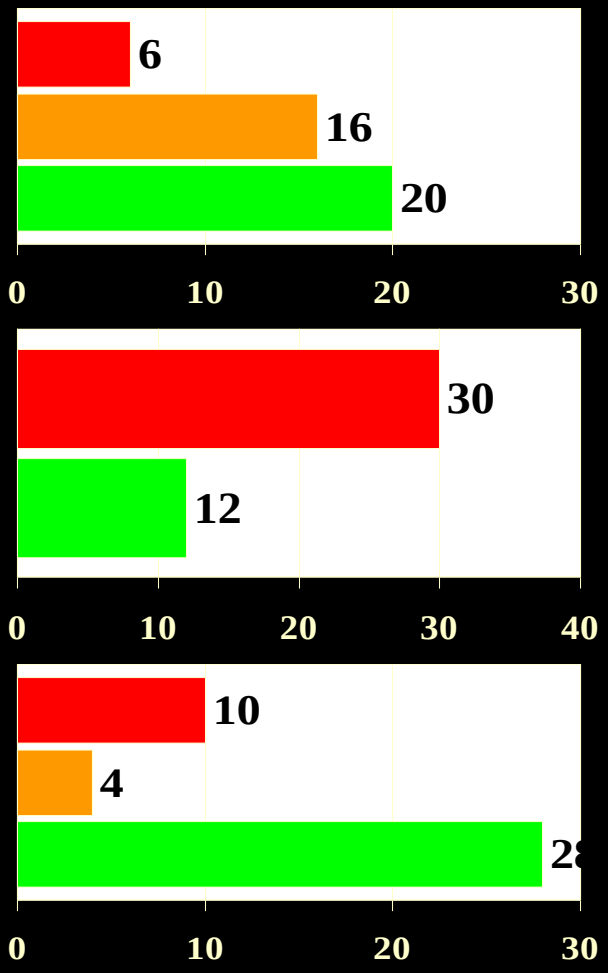
0 No 1 Unclear 2 Yes

F) Was there any attempt at blinding (for example, independent assessor)?

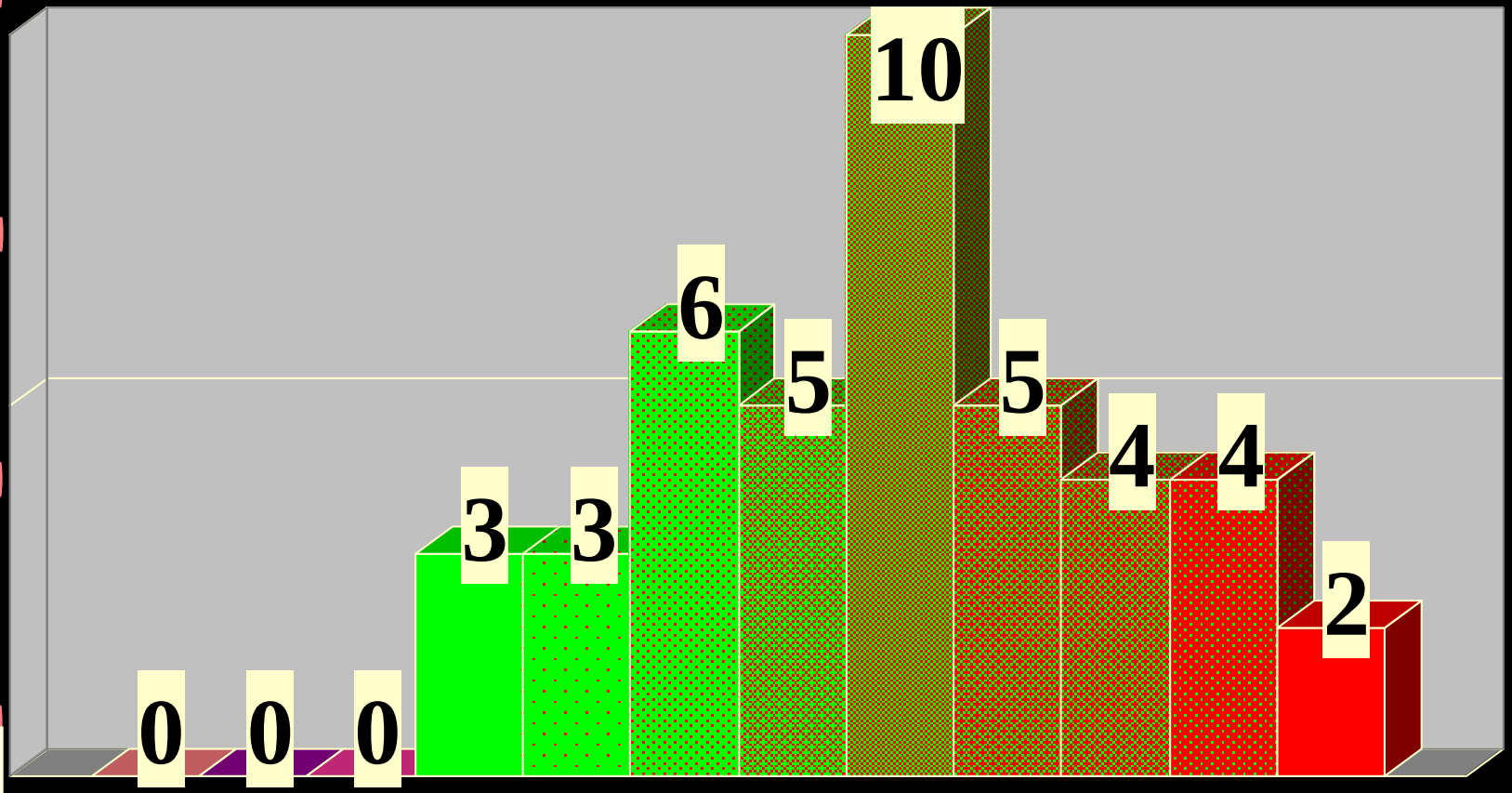
0 No 1 Yes

G) Was the statistical analysis appropriate?

0 No 1 Unclear 2 Yes



Methodologic scoring of RCTs (n=42)



Method of a review- Data synthesis

1. Two reviewers work independently, and in duplicate.
2. Appraise:

- patient age
- withdrawals by group
- reasons for withdrawals.
- primary outcomes for all time points mentioned in the study report.

Which outcome criteria?

Interventions comparing oral implants with different materials, shapes and surface properties

1) Implant mobility and implant removal of stable implants dictated by progressive marginal bone loss
2) Implant fracture and other mechanical complications that do not allow the use of the implants
3) Radiographic marginal bone level changes on standardised intra-oral radiographs

Which outcome criteria?

Oral hygiene procedures self and professionally administered, local and systemic therapeutic agents for the maintenance of oral health

1) Plaque
2)Marginal bleeding
3) Probing pocket depth
4) Probing “attachment” level
5) Radiographic marginal bone level changes on standardised intra-oral radiographs

Measures relative to treatment outcomes

Perceived/self reported:

- Adaptation to prosthesis (satisfaction/dissatisfaction)
- Appearance
- Function (chewing, speech)
- Dietary significance (intake, selection)
- Health
- Quality of life (psyche, wellbeing, self esteem)
- Social activity

Perceived/self reported:

- Appearance
- Function
- Dietary significance
- Health indices *
- HRQL indices*
- Social activity
- Activity*

Study aims

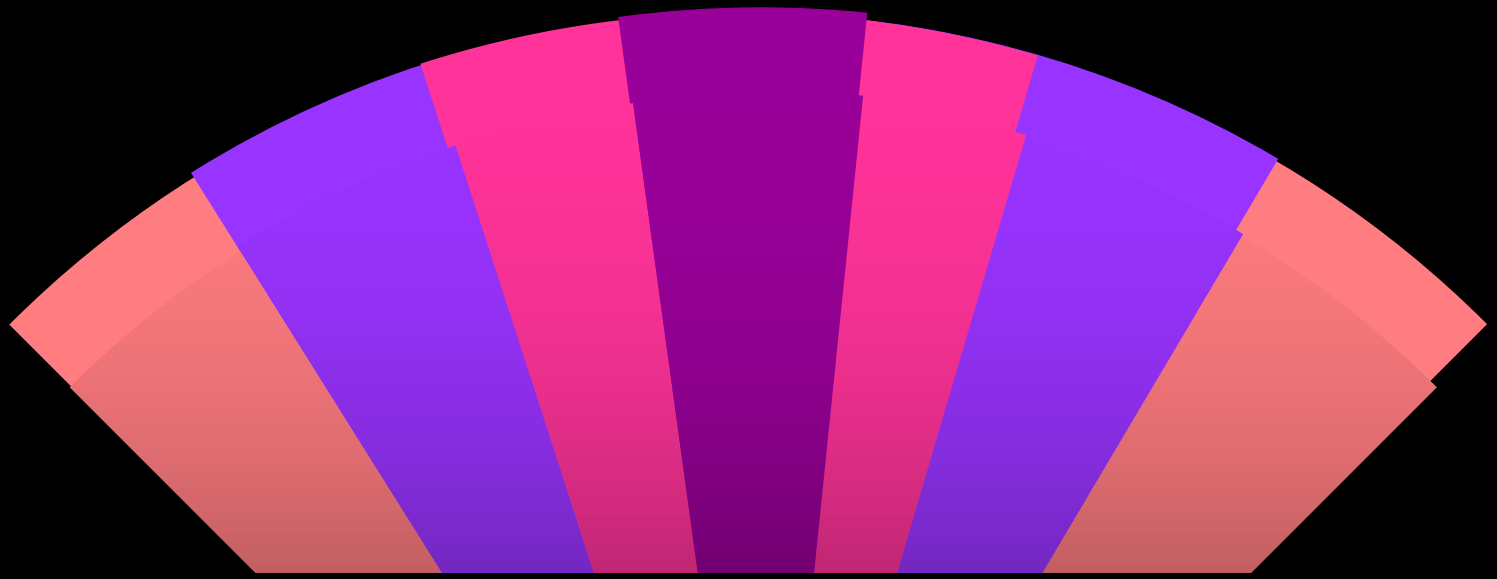
- Conventional versus implant prosthodontics
- Prosthesis characteristics
- Implant-prosthesis connection characterstics
- Implant characteristics
- Implant surgery techniques
- Guided bone regeneration
- Maintenance

Study aims - Prosthesis characteristics

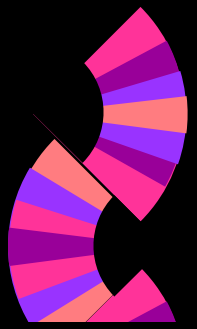
- Prosthesis type
  - Stress-breaker vs non-stress breaker
  - Splinted vs unsplinted connection
- Implant-prosthesis connection
  - Fixed vs overdentures
  - Hybrid versus ball-attachment
  - Different overdenture attachments
  - Laser-welded vs cast Ti-framework

Study aims - implant characteristics

- Implant location
  - Wide vs minimised spaces
- Implant number
  - 2 vs 4 implants supporting overdenture
- Implant type
  - Self-tapping vs standard
  - Rough vs smooth surface
  - Titanium vs Hydroxyapatite
  - Staple vs 2 & 4 implants

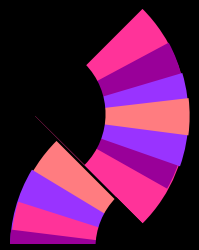


Patient centered criteria ?



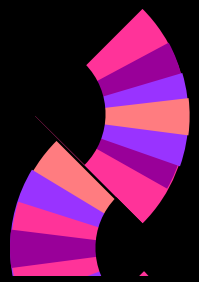
Perceived/self reported: Adaptation to prosthesis (satisfaction/dissatisfaction with prosthesis)

- Conventional denture vs implant: less. Boerrigter, Geertman, Kwakman, Meijer, de Grandmont, Kapur
- Magnet attach vs. ball attach: less. Burns, Davis, Naert
- Magnet attach vs. clip attach: less. Naert
- Ball attach. vs clip attach: less/similar. Bergendal, Naert, Tang, Wismejer
- 2 Ball attach vs 4 ball attach: similar. Wismejer
- Bar-clip attach vs. fixed bridge: less. de Grandmont, Feine
- Ball attach vs transmandibular: similar.Geertman, Kwakman



Perceived function - chewing ability

- Conventional denture vs implant: less or similar. Awad, Kapur, Boerrigter, Geertman-Kwakman-Meijer, Feine-de Grandmont
- Magnet attach vs. ball attach: less. Davis, Burns, Naert
- Magnet attach vs. clip attach: less. Naert
- Ball attach vs clip attach: better/ similar. Naert, Tang, Wismejer
- No occlusion vs occlusal morphology: less. Khamis
- 2 Ball attach. Vs 4 ball attach: similar. Wismejer
- Bar-clip attach vs. fixed bridge: less. deGrandmont, Feine
- Ball attach vs transmandibular: similar. Geertman

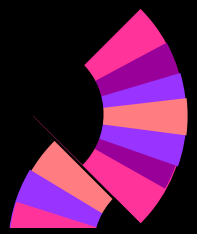


Perceived/self reported: Pain

- Conventional denture vs implant: less or similar. Awad, Geertman
- Ball attach. Vs clip attached implant: similar. Wismejer
- 2 Ball attach. Vs 4 ball atached implant: similar. Wismejer
- Ball attach vs transmandibular implant: less. Geertman

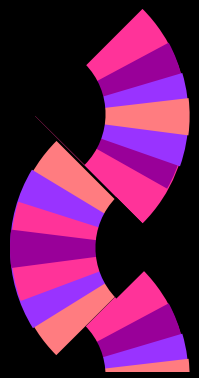
Perceived/self reported: appearance

- Conventional denture vs implant: less. Boerrigter-Geertman
- Magnet attach vs. ball attach implant: similar. Naert
- Magnet attach vs. clip attach implant: less or similar. Naert
- Ball attach vs clip attach implant: less or similar. Naert, Tang
- Abutment appraisals: similar. Andersson, Kemppainen
- Bar-clip attach vs. fixed bridge implant: less or similar. Feine
- Ball attach vs transmandibular implant: similar. Geertman



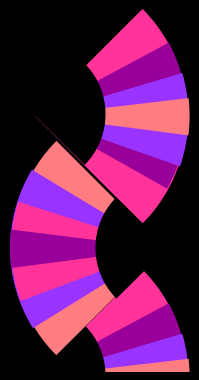
Perceived function - speech

- Conventional denture vs implant: less or similar. Boerrigter-Geertman, Kapur
- Magnet attach vs. ball attach: less. Burns, Naert
- Magnet attach vs. clip attach: less or similar. Naert
- Ball attach vs clip attach: better or similar. Naert, Tang, Wismejer
- 2 Ball attach vs 4 ball attach: less or similar. Wismejer
- Ball attach vs transmandibular: similar. Geertman
- Bar-clip attach vs. fixed bridge: less. Feine



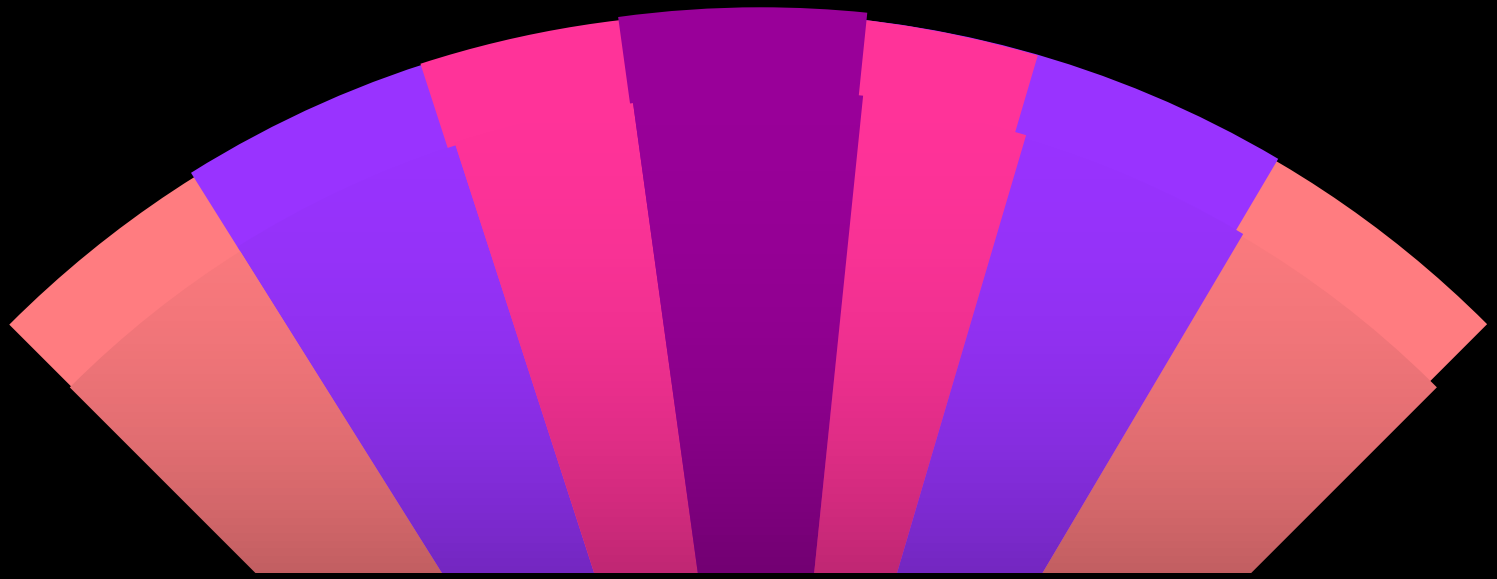
Quality of life (psyche, wellbeing, self esteem)

- Conventional denture vs implant: less or similar. Awad, de Grandmont, Bouma
- 2 Ball attach vs 4 ball attach: similar. Wismejer
- Ball attach vs clip attached: similar. Tang
- Bar-clip attach vs. fixed bridge: similar. de Grandmont

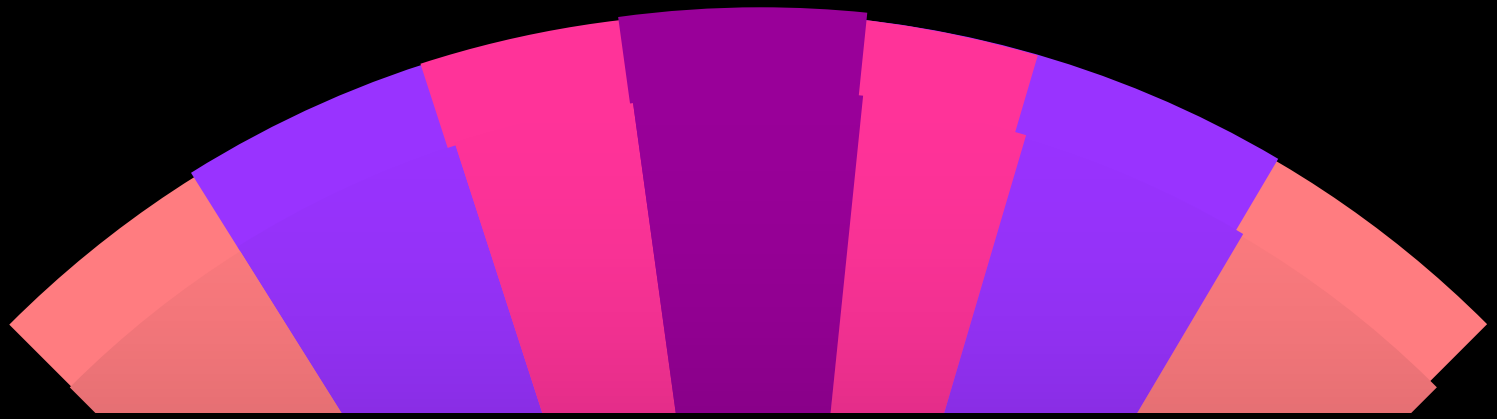


Observed/examined: Function (chewing efficiency, speech)

- Conventional denture vs implant: less or similar. Geertman, Garrett
- Occlusal morphology: similar. Khamis
- Ball attach. vs clip attach : similar. Tang
- Ball attach vs transmandibular: similar. Geertman
- Bar-clip attach vs. fixed bridge: similar. Feine



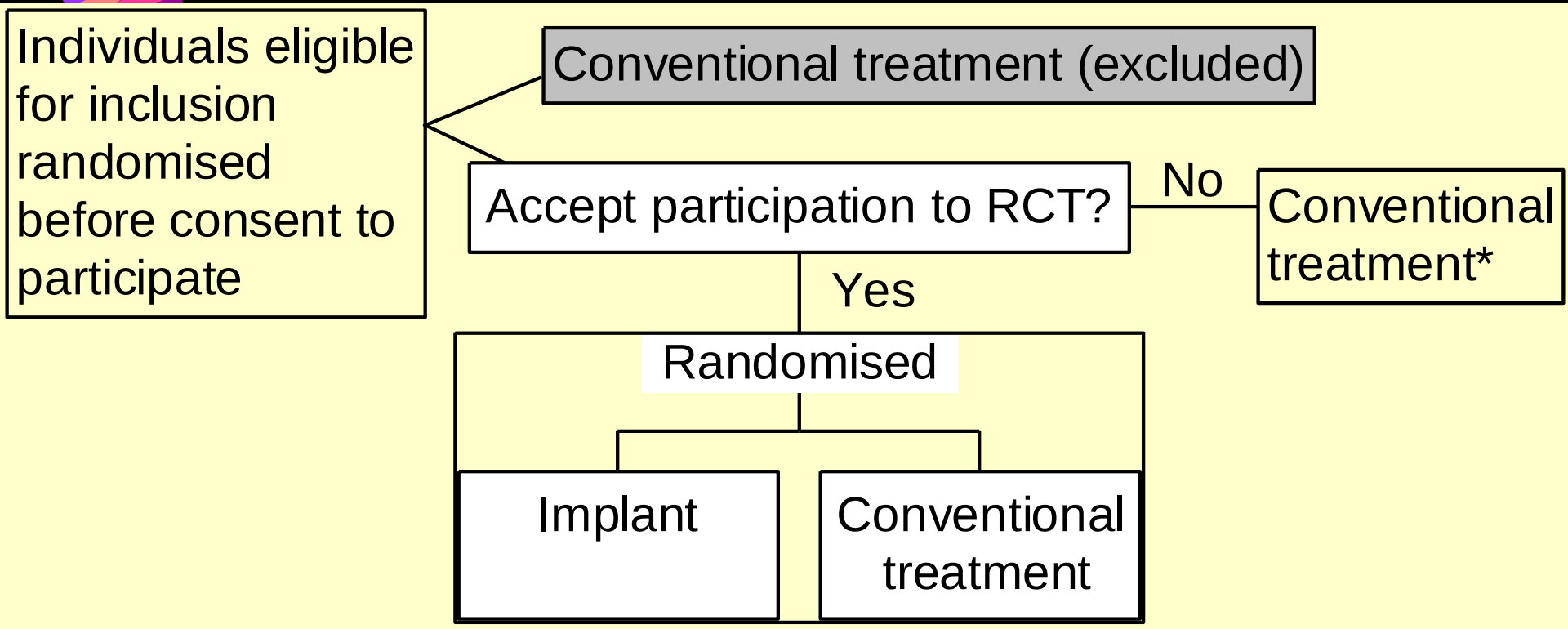
Why so few Randomised Controlled Trials in Prosthetic Dentistry ?



Randomised Controlled Trials in Prosthetic Dentistry need to take into account Patient Preferences

Zelen design

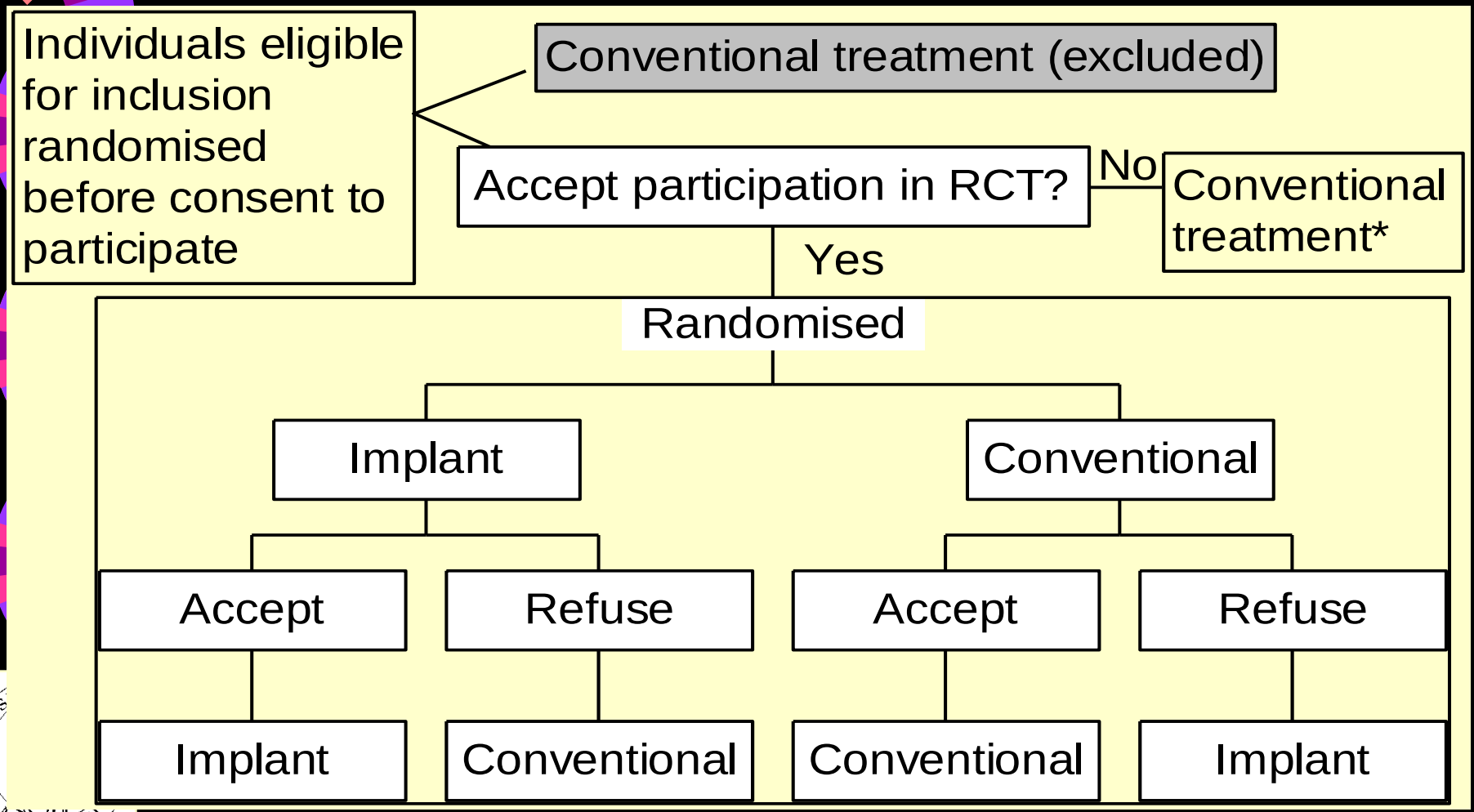
Zelen M. A new design for randomized controlled trials. N Engl J Med 1979; 300: 1242-45. Advantage that almost all eligible individuals are included. Allows evaluation of the true effects of offering experimental interventions to patients. Disadvantage that it is an open trial, and statistical power affected if high proportion of participants choose to have the standard treatment.



* Given conventional treatment, but analysed as if they have received exp. treatm.

Zelen double randomised consent design

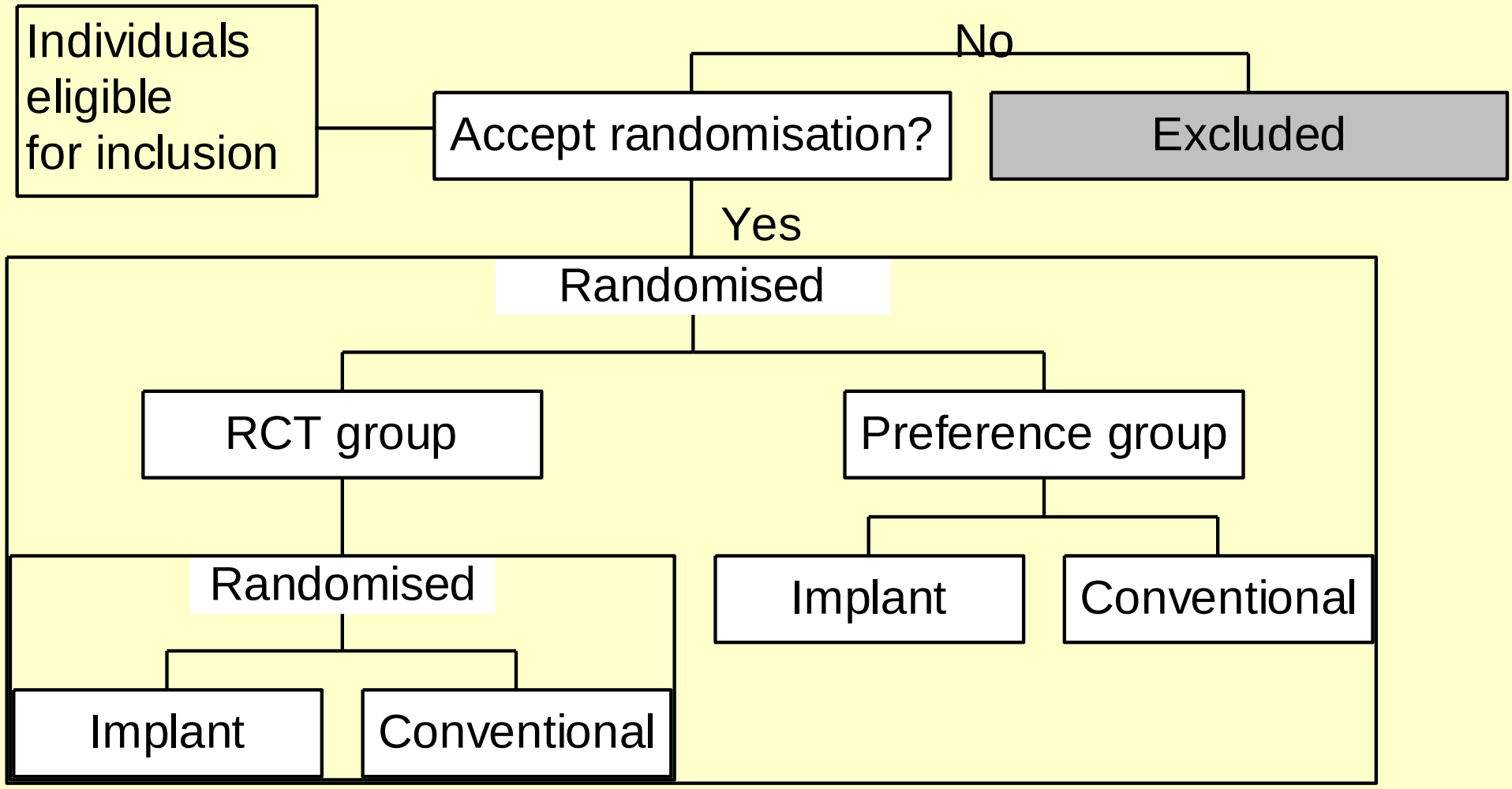
Olswchewski et al., 1985. Ethical concerns overcome by offering the opportunity to switch to other group



- ***Given conventional treatm., but analysed as if they have received exp. treatm.***

Wennberg design

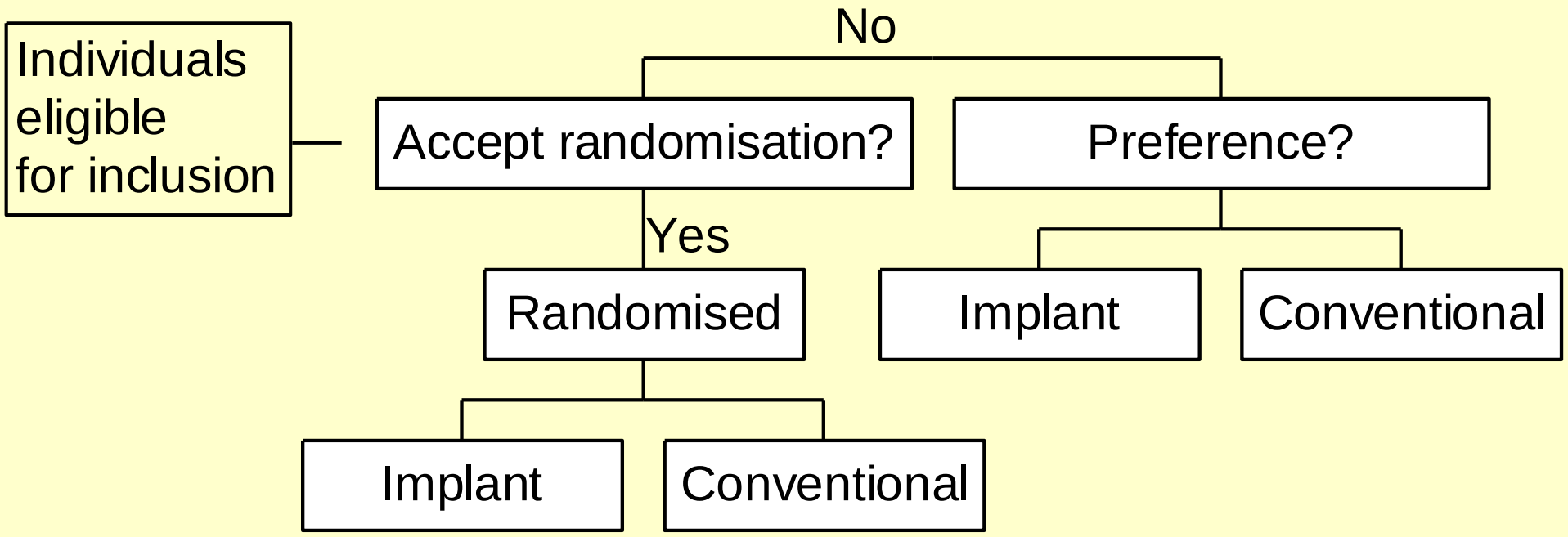
Include individuals who agree to be randomised



Comprehensive cohort design

Olschewski et al., 1985; Brewing & Bradley, 1989.

All participants are followed up, regardless of randomisation status. Outcomes of RCT and cohort groups can be compared. Ideal where it is likely that many patients will refuse, because patients or operators have a strong preference for one intervention. A disadvantage is no status of differences in baseline characteristics in the RCT and preference groups. Satisfaction with existing conditions very likely influence.



Feine & Awad design

Feine J, Awad MA. Community Dent Oral Epidemiol 1998.