IDEAL – a continually improving work in progress

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Registries in all IDEAL stages

Devices
Intervention development & stabilisation
Systematic review of intervention design & delivery in pragmatic and explanatory RCTs

129 (80%) described intervention
43 (26%) referred to previous publication
39 (24%) described criteria for modification
7 (4%) described criteria for discontinuation

Blencowe N, Boddy A, Harris AP et al 2015 102(9):1037-47
British Journal of Surgery
A full technical description of the new procedure

1. ........in sufficient detail to allow an equivalently skilled operator to reproduce it.

2a. ........ an account of when, why and how modifications to technique were made.......... 

2b. ........minor differences in technique.

3. ........stable and reproducible.
Need ways of describing procedures, modification & stabilisation
Typology what is it?

Showing results for typology what is it
Search instead for Typology what is it?

typology
/tɪpəˈlɒdʒi/ (↓)
noun
1. a classification according to general type, especially in archaeology, psychology, or the social sciences.
   "a typology of Saxon cremation "cools"
2. the study and interpretation of types and symbols, originally especially in the Bible.

Translations, word origin, and more definitions

N Blencowe PhD thesis
Description, standardisation & monitoring
Typology development

1. Read initial subset of trial reports to develop initial framework

2. Re-categorise and refine

Provides methods to:
- Consider overall purpose
- Document intervention components

Medical & surgical journals 2010-2011 (n=12)

RCTs of surgical interventions

80 RCTs
160 interventions
Consider the overall technical purpose of an intervention?

Exploration
Resection
Reconstruction

Blencowe N, Mills N, Cook JA et al 2016 103(10):1377-84
British Journal of Surgery
What are the components of an intervention?

- Access
- Dissection
- Resection
- Reconstruction
- Closure

Steps
Steps
Steps
Steps
Steps
Literature analysis & expert opinion
Non-participant observation, video and interviews
The By-Band Study

Eligible for By-Band

Bypass
N=362

Band
N=362

What about new / competing interventions
Sleeve gastrectomy when By-Band started

- Novel & changing
- Safe?
- Not in widespread use
- Too early for RCT
Changes in rates of surgery

Bypass
3000
3500
4000
59.9%
56.4%

Sleeve
2000
2500
3000
12.0%
27.2%

Band
1500
1000
500
8.2%
12.0%

Years:
2009
2010
2011
2012
2013
What was evolving?

Width of gastric sleeve

Use & size of bougie
Original article

International Sleeve Gastrectomy Expert Panel Consensus Statement: best practice guidelines based on experience of >12,000 cases


Received October 26, 2011; accepted October 27, 2011
Survey on laparoscopic sleeve gastrectomy (LSG) at the Fourth International Consensus Summit on Sleeve Gastrectomy

Michel Gagner • Mervyn Deitel • Ann L. Erickson • Ross D. Crosby

Published online: 4 August 2013
© Springer Science+Business Media New York 2013
Original article

Fifth International Consensus Conference: current status of sleeve gastrectomy

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Received January 14, 2016; accepted January 21, 2016
By-Band to By-Band-Sleeve
Eligible for By-Band-Sleeve

- Bypass
  - N = 447
- Band
  - N = 447
- Sleeve
  - N = 447

Rogers *et al.* Adaptation of the By-Band randomized clinical trial to By-Band-Sleeve to include a new intervention and maintain relevance of the study to practice. British Journal of Surgery. *In press* 2017
11 UK centres
Registries in all IDEAL stages

Devices
Methods for understanding intervention development & stabilisation
Acknowledgements

• NIHR HTA project grant 09/127/53
• Royal College of Surgeons Bristol Surgical Trials Centre
• MRC ConDuCT-II Hub for Trials Methodology Research

... and our many NHS partners

Department of Health Disclaimer: The views and opinions expressed herein are those of the authors and do not necessarily reflect those of the NIHR HTA, NHS or the Department of Health.
Conference 2018 Bristol, UK

The IDEAL Collaboration

Idea, Development, Exploration, Assessment, Long-term follow-up