

# **A systematic review of intervention design and delivery within pragmatic and explanatory surgical RCTs**

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## **Abstract**

### **Background**

Surgical interventions are complex with multiple components, which requires consideration in trial reporting. Pragmatic trials may require less detail than explanatory studies, which establish how interventions work under controlled conditions. This review examined the reporting of details about surgical interventions in randomised controlled trials (RCTs) within the context of explanatory and pragmatic study designs.

### **Methods**

Systematic searches identified RCTs of surgical interventions published between 2010 and 2011. Included studies were categorised as predominantly explanatory or pragmatic. The extent of intervention details in the reports were compared with the CONSORT statement for reporting trials of non-pharmacological treatments (CONSORT-NPT). CONSORT-NPT recommends reporting the descriptions of surgical interventions, whether they were standardised and adhered to (items 4a,b,c). Reporting of the context of intervention delivery (items 3,15) and operator expertise (item 15) were assessed.

### **Results**

Of 4541 abstracts and 131 full text articles, 80 were included (of which 39 were classified as predominantly pragmatic), reporting 160 interventions. Descriptions of 129(81.6%) interventions were provided. Standardisation was mentioned within 47(29.4%) studies and 25(31.3%) reported measurement of adherence to at least one aspect of the intervention. 71(88.8%) studies provided some information about context. Operator expertise was

documented in 39(24.3%) articles. Reporting standards were similar in trials classified as pragmatic or explanatory.

## Conclusion

The lack of detail in trial reports about surgical interventions creates difficulties in understanding which operations were really evaluated. Methods for designing and reporting surgical interventions in RCTs, accounting for the overall study design, are required. This should allow better implementation of trial results into practice.

## Introduction

Well designed and conducted randomised controlled trials (RCTs) are essential to assess the effectiveness of interventions, allowing clinicians to make evidence-based treatment decisions. High quality reporting of RCTs is necessary to facilitate transparency, critical appraisal and to allow results to be implemented in practice. The CONSORT (Consolidated Standards for Reporting Trials) initiative provides a checklist of reporting standards and its use has been endorsed by many major journals<sup>1</sup>, leading to improvements in RCT reporting<sup>2</sup>. Since then, a CONSORT extension for Non-Pharmacological Treatments (CONSORT-NPT)<sup>3</sup> has been developed in recognition that many healthcare interventions are complex, ~~consisting of multiple components that may act independently or inter-dependently to influence outcomes~~ **including surgery**. ~~CONSORT-NPT~~ **CONSORT-NPT** ~~These guidelines~~ recommends reporting precise details of the intervention and its components (item 4a), information about standardisation and delivery (items 4b and c), descriptions of study context (items 3 and 15) and the expertise of care providers (item 15). These items aim to provide information such that interventions displaying a positive treatment effect can be subsequently implemented in

routine practice. Whilst important to describe interventions in RCTs, the overall type of trial design ~~and whether the scope of a study is predominantly explanatory or pragmatic~~ may influence this detail.

Explanatory trials aim to test the safety and/or efficacy of interventions under optimal ~~and controlled~~ conditions. In surgery, explanatory trials usually comprise single centre studies with short-term technical or adverse event outcomes, and strict inclusion criteria ~~for patients and participating surgeons~~<sup>4</sup>. Conversely, pragmatic trials are designed to evaluate the effectiveness of interventions in the 'real world', thus producing results that can be more readily generalised to routine practice. Pragmatic trials therefore usually involve multiple hospitals, measure endpoints of relevance to patients and have wide inclusion criteria. Whilst some methodological guidance recommends that interventions in explanatory and pragmatic trials are described and delivered differently<sup>5</sup>, it is uncertain how this should be incorporated into surgical RCTs. Surgical interventions are made up of many different components ~~and accompanying concomitant interventions~~, all of which may influence the estimated treatment effect. Describing all of the details, as well as how they are standardised and monitored, may not be practical within trial reports<sup>6</sup>. Moreover, there may be circumstances where detailed information is not required. In pragmatic studies, for example, it may ~~only be~~ **not be** necessary to ~~provide a general outline of~~ **describe** the procedure **at all** ~~(or no information at all)~~, meaning they can be performed according to the preferences of operating surgeons. Conversely, explanatory studies may contain ~~very~~ detailed information about all aspects of ~~an interventions and concomitant interventions~~, including how they should be standardised and delivered<sup>6, 7</sup>. In view of these challenges, this study examined reporting standards of the interventions in RCTs in surgery and considered

how interventions were reported within the context of the overall study design (pragmatic or explanatory).

## **Methods**

A systematic review identified reports of RCTs of surgical interventions. Reporting of intervention descriptions, standardisation and adherence was undertaken in detail. RCTs were classified as predominantly pragmatic or explanatory.

### **Search strategy**

Online archives of the top six journals ranked by impact factor, for each of general medicine and surgery (Appendix 1), were hand searched to identify studies published between January 2010 and December 2011<sup>8</sup>. The search was limited to two group RCTs of human subjects involving at least one surgical intervention. Abstracts and conference proceedings were excluded because of the high probability of incomplete data due to limited space.

### **Study selection**

Surgical interventions were defined as procedures involving an incision with instruments usually performed in an operating theatre and normally involving anaesthesia and/or respiratory assistance<sup>9</sup>. Trials of surgical technique, access, technology and instruments from any surgical discipline were included. Endoscopic, radiological and dental interventions were excluded, in order to focus upon the reporting standards of surgical interventions conforming to the above definition. Non-randomised sub-studies from RCTs and papers reporting long term follow-up data were excluded. Full papers of abstracts were screened

by one researcher and to ensure consistent application of inclusion criteria, a second researcher independently hand searched 75% of journal archives. **This percentage was selected because the search strategy involved screening journal contents pages, the layout and display of which differed between journals. It was therefore considered important to ensure that information was not missed. Reliability between researchers was high, meaning that double screening of all contents pages was not felt to be necessary.** Where available, trial protocols were obtained by email contact with authors or from the web, and analysed in the same way as full text articles.

### **Data extraction**

Data were extracted independently by two reviewers and disagreements were resolved through discussion or referral to a third reviewer where necessary.

#### *Details of included studies and categorization of trial design*

General details about the trials (e.g. type of surgical sub-specialty, sample size, patients and outcomes) and availability and format of additional trial information (e.g. full trial protocol, web link, published article, or other documents obtained by contacting authors) were recorded. Trials were categorised as 'predominantly pragmatic' or 'predominantly explanatory' in order to consider intervention reporting within this framework. Currently, formal methods to undertake this at the reporting stage are not available; therefore, reports were independently assessed for classification by two authors (NB and JMB) against pre-determined criteria informed by the PRECIS guidelines for designing pragmatic and explanatory trials<sup>4</sup>. **PRECIS consists of 10 dimensions with a visual analogue scale**

representing the pragmatic/explanatory continuum. Of these dimensions, six were examined within this review (reporting of expertise, adherence, and intervention standardisation for the intervention and comparator) and were therefore not used to decide whether a study was predominantly pragmatic or explanatory. The remaining PRECIS dimensions were used to decide on the overall design: nature of the primary endpoint and its analysis, intensity of follow-up, and the breadth and number of inclusion and exclusion criteria (Table 1). Additionally, the number and type of participating centres was included in this assessment. A 'difficult to classify' category was only used where the overall trial design could not be determined because either the nature of the primary outcome conflicted with other features of study design. Examples of reports meeting the criteria for the 'difficult to classify' category include RCTs with short-term technical endpoints that were otherwise pragmatic (i.e. multiple centres, wide inclusion criteria and few exclusion criteria) and vice versa. Disagreements were resolved through discussion.

#### *Intervention description, standardisation and adherence (item 4)*

Reporting of intervention and comparator details (item 4a) was assessed by recording whether any description was provided, defined as anything more than the name of the intervention. For example, a study reporting that 'patients underwent a hernia repair' would not constitute provision of a description whereas a study describing any information about the incision, type of suture or method of closure, was classified as provision of an intervention description (regardless of how much information was reported). The presence of citations to other materials (e.g. technical reports or videos) describing the operation was recorded separately. Reporting of whether surgical interventions were standardised for

delivery in the trial was recorded as yes/no (item 4b) and any reasons for standardisation documented. Details of methods used to standardise the procedures were recorded.

Reporting of information about measurement of treatment adherence was assessed as yes or no and details of processes used to measure adherence, and methods to improve adherence, were recorded. Details of studies reporting crossover to the other trial group (i.e. the number of patients receiving the intervention intended for those in the opposite trial group) were also assessed.

#### *Intervention context (items 3 and 15)*

Information about trial context was assessed by extracting details of the number and type of centres (e.g. primary, secondary or tertiary) and study entry criteria for centres, including the rationale for these criteria, if available.

#### *Expertise (item 15)*

Details about operator expertise were documented by recording whether trials reported surgeons' qualifications, annual caseloads or the number of procedures previously performed. The number of surgeons undertaking procedures in each trial group was recorded, including whether they performed interventions within one or both trial groups. Information about study entry criteria for surgeons was extracted, such as completion of a certain number of procedures, attendance of formal training, reading or watching study materials (e.g. handbooks or videos) or independent reviews of operative techniques.



### *Quality assessment*

The Cochrane Collaboration's risk of bias tool was used to appraise the quality of included RCTs by assessing internal validity, which comprises sequence generation and allocation concealment, blinding of participants and outcome assessment, incomplete outcome data and selective outcome reporting<sup>10</sup>. Judgments were made independently by two reviewers and disagreements were resolved through discussion or referral to a third reviewer where necessary.

### **Data analyses**

Medians and ranges were calculated for the number of participating patients. Reported data were compared according to trial design (i.e. pragmatic or explanatory) and reports within the third 'difficult to classify' category were not included. Formal statistical comparisons were not undertaken because the overall aim of the review was to summarise reporting standards.

## **Results**

### **Details of included studies and categorization of trial design**

Of 4541 abstracts and 131 full text articles, 80 studies were included reporting 160 interventions. Included RCTs reported outcomes from a total of 28 847 patients (range=21-2522) from several specialties (Figure 1)<sup>11-90</sup>. Studies were mostly published in the British Journal of Surgery (n=25), followed by the Annals of Surgery (n=17) and the New England Journal of Medicine (n=14). Information relating to sample size calculations and the primary outcome were provided in 71 (89.9%) and 75 (94.9%) studies, respectively. Seventy eight

studies (98.7%) documented inclusion criteria for patients and 75 (94.9%) provided evidence of ethical approval. Supplementary information was obtained for 31 studies (38.8%) in the form of a written protocol (n=19), web appendix (n=11) or trial website address (n=1).

Of the included studies, 30 were classified as predominantly explanatory, 39 pragmatic and it was not possible to classify 11 of the studies in this way<sup>19, 26, 33, 44, 47, 59, 67, 81, 82, 88, 89</sup>. **This was because they had a design that was predominantly pragmatic but the primary end point was a very short-term technical endpoint - or vice versa. In addition, there was no documented explanation or rational for such polarisation in trial design (i.e. why such a technical endpoint was selected for an RCT with an otherwise pragmatic design, or vice versa).**

#### **Intervention description (item 4a)**

Reporting of intervention descriptions is summarised in Table 2. At least some description was provided for 129 (80.6%) of the 160 interventions. Of the 80 RCTs, 54 described both interventions, 15 described one of the two interventions, and in 11 studies neither intervention was described. Descriptions ranged from single sentences to detailed paragraphs. Single sentences consisted of general statements about a procedure, for example 'the open tension-free mesh hernioplasty was performed according to Lichtenstein.'<sup>53</sup> Where more details were provided, these consisted of specific instructions regarding operative steps:

'For open colorectal resection, transverse suprapubic or midline incision was used depending on the route of previous surgery. After exploration of the abdomen, the ureter was identified crossing the pelvic brim on the left, and mobilization was continued inferiorly to open the pararectal space. The right mesocolon was then opened and dissection extended down to the right pararectal space....A linear cutter 45mm was introduced and applied transversely across unaffected distal rectum.'<sup>30</sup>

There were 41, nine, and two papers that referenced published technical reports, pictures or videos to support the intervention description.

#### **Intervention standardisation (item 4b)**

Some 47 of 160 (29.4%) of interventions in the included trials were reported to be standardised in some way (Table 2). Although 30 (63.8%) of these contained a statement that the intervention had been standardised, no information was provided about how this was achieved (Table 3). In the remainder (n=17, 36.2%), methods of standardisation were described although it was unclear in all of these reports whether or not these were implemented successfully.

Examples of methods to standardise intervention delivery included holding pre-trial technical workshops for surgeons to attend<sup>16, 35, 68, 71, 72</sup>, provision of training videos<sup>16, 17, 68</sup>, photographs<sup>50</sup> or a detailed operative manual<sup>33</sup>, and in one trial participating surgeons were directly reviewed by other surgeons<sup>50</sup>. In five studies the authors stated that standardisation was not required (3.1%). This decision was justified in two, describing the need for generalizability of the findings<sup>81</sup> and a lack of proven association between operative technique and outcomes<sup>24</sup>. Descriptions of the standardisation processes were limited to just one sentence in all except one study, which published an accompanying paper describing the methods used<sup>39</sup>. The paper described how a consensus meeting with 40 experienced surgeons was held before the trial, during which they were asked to review videos of each other's operative techniques and propose a standardised procedure. From the meeting the group agreed common elements and variations of the procedure and it was recommended that these were then implemented in the trial. Adherence to these standards

during the trial was also reported, although the ways in which adherence was measured were not described.

#### **Treatment adherence (item 4c)**

There were 58 (72.5%) studies reporting rates of crossover, and another four reporting that some participants did not receive an intervention at all. Some 22 (27.5%) studies reported adherence to at least one aspect of the intervention description. Examples of methods for monitoring adherence included independent review of radiographs to establish gallstone clearance following endoscopic retrograde cholangio-pancreatography<sup>75</sup>, intra-operative photography to document three key operative steps during pancreatectomy<sup>33</sup>, intra-operative biochemical monitoring to confirm excision of the parathyroid gland<sup>58</sup> and review of videotapes and operative notes following laparoscopic hernia repairs to identify protocol deviations<sup>47</sup>. In the latter example, however, the steps constituting protocol deviations were not reported.

#### **Intervention context (items 3 and 15)**

The 80 reports included both single and multicentre trials (range=1-177, median=3), although this information was not reported in 10 (12.5%) studies (Table 4). The nature of included centres was reported in 26.2% (n=21) studies. Few details were available and some used terms such as 'community hospitals'<sup>60</sup>, 'public hospitals'<sup>76</sup> or 'government health centres'<sup>71, 72</sup>, but the meaning of these terms were not explained. Some provided more detailed information, such as 'expert centres specializing in hepatobiliary surgery'<sup>77</sup> and 'centres had to be either academic units or affiliated with a university'<sup>39</sup>.

Very few studies reported the usual caseload (n=2, 2.6%) or entry requirements (n=5, 6.2%) for the centres to participate in the trial. Verbatim examples of eligibility include 'centres were required to have a team consisting of a neurologist, interventionist, surgeon and a research coordinator'<sup>11</sup>, and 'centres had to perform at least 10 resections per year'<sup>33</sup>. Neither studies nor accompanying documents provided rationale for such eligibility criteria.

## **Expertise**

For a third of interventions (n=55, 34.4%), some data was provided about the expertise of personnel undertaking them (Table 5). Only 39 (24.4%) reported the number of personnel delivering each intervention with 14 studies (17.5%) clarifying that the same operators delivered interventions in both trial groups. The grade of personnel was provided for 29 (18.1%) interventions. Some other generic descriptions of expertise were provided; for example, 'wide experience' or 'qualifications' without any explanation of the meaning of these terms.

The standards required for a surgeon to participate in a trial were reported for 29 interventions (18.1%). A variety of methods were used, including attendance of training courses (n=11), provision of audit data with a morbidity or mortality threshold (n=2), previous completion of a certain number of procedures (n=15), watching a procedural video (n=2), observing other surgeons (n=2), submission of a curriculum vitae (n=2), a specific annual workload volume (n=1), and participation in a previous study (n=2).

## **Reporting according to study design (explanatory vs pragmatic)**

There were few differences in the description, standardisation and monitoring of interventions in the included trials, when categorised as predominantly pragmatic or explanatory. Descriptions were provided for 46 of 60 (76.7%) interventions within explanatory studies, compared with 63 of 78 (80.8%) interventions within pragmatic studies. Amongst explanatory studies, 21 of 60 (35.0%) interventions were reported as standardised compared with 16 of 78 (20.5%) pragmatic studies. Permission to undertake procedures according to surgeons' individual preferences was reported for two trials (explanatory=1, pragmatic=1). In 10 (33.3%) of explanatory and 14 (35.9%) of pragmatic RCTs, reporting of adherence to the intervention was described. Four of the explanatory RCTs and one pragmatic RCT reported trial entry criteria for centres. Entry criteria for surgeons were specified in seven (23.3%) explanatory and 10 (25.6%) pragmatic RCTs.

### **Quality assessment**

Across all domains of bias except 'incomplete outcome data', the majority of studies were judged to be 'unclear'. The largest number of 'high risk' judgements was found for blinding of participants or personnel (n=20) and outcome assessment (n=16), respectively. Conversely, 'sequence generation' (n=29) and 'outcome data' (n=50) received the most judgements of low risk, respectively.

### **Discussion**

This systematic review has summarised reporting standards of details about how surgical interventions are described in trials. ~~Trials were categorised as predominantly pragmatic or explanatory and reporting of surgical interventions, contextual factors, and operator~~

~~expertise considered within these contexts. The review~~ It found that although some description of the surgical intervention was provided for 129 of the 160 included interventions, in the remainder only the name of the intervention was given. ~~Trials providing only intervention names were not especially pragmatic in general design and justification for the lack of intervention description was not given.~~ Information relating to how and whether the intervention was standardised in the trial was reported for only 44 (27.5%) interventions; ~~however, half of these did not explain what was meant by 'standardisation' or how this was achieved.~~ This lack of detail of the surgical intervention in the trial reports and uncertainty of what was performed means that it is difficult to know what operation was really evaluated and under what conditions, and how they should be implemented in practice to achieve the described treatment effect.

The reporting quality of information within RCTs relating to the complexity of surgical interventions has been previously examined in five systematic reviews, published between 2006 and 2013<sup>91-95</sup>. Three of the studies were published before CONSORT-NPT was available<sup>91, 93, 94</sup> and the other two sought to establish whether this guidance had influenced reporting standards<sup>92, 95</sup>. They showed that few trials met reporting standards, which may be partly due to deficiencies in the way that articles were selected and assessed. One review only included papers from four surgical subspecialties and whilst the other selected articles from medical and surgical journals, all items of the checklist were assessed meaning that those specific to the reporting of non-pharmacological treatments (i.e. descriptions and standardisation of interventions, and adherence) were not explored in detail<sup>92, 95</sup>. Another possible reason for the poor reporting standards is that the CONSORT-NPT and explanatory notes are unclear. For example, neither term 'standardisation' or 'adherence', are

explained and whilst they require 'precise details of both the intervention and comparator' to be reported no definition for the term precise is given. The current study has attempted to understand and improve this by looking in detail how intervention descriptions and other items are documented.

Since this review was undertaken, guidance pertaining to intervention descriptions within RCTs (TIDieR) has been published<sup>96</sup>. TIDieR recommends that information other than just the name or phrase describing the intervention is reported such as duration, intensity, mode of delivery (and by whom), as well as the process of intervention delivery. The guidance explains the latter as 'processes, activities or procedures the intervention provider/s carried out' which may include a 'sequence of steps to be followed'. It does not, however, explain how these details should be established and this is of particular importance for surgical interventions, which are complex. Moreover, although information about modifying interventions to specific participants is recommended, this is not discussed in relation to particular settings or study designs. It is arguably unrealistic (and unnecessary) to expect that pragmatic studies, which reflect the effectiveness of interventions in the real world, would provide the same level of detail as explanatory studies, which aim to provide tight control and assess efficacy under ideal conditions. This presents a dilemma for RCTs in surgery, in terms of maximising generalizability and translation of results whilst maintaining integrity and scientific rigour. This means that even in a pragmatic setting it may still be necessary to achieve the key goal of RCTs; namely to ensure comparable study groups that differ only by the interventions being evaluated, so that outcomes can be attributed to the effects of these interventions. This may require pragmatic RCTs to describe the interventions in enough detail such that participating surgeons (delivering the interventions)



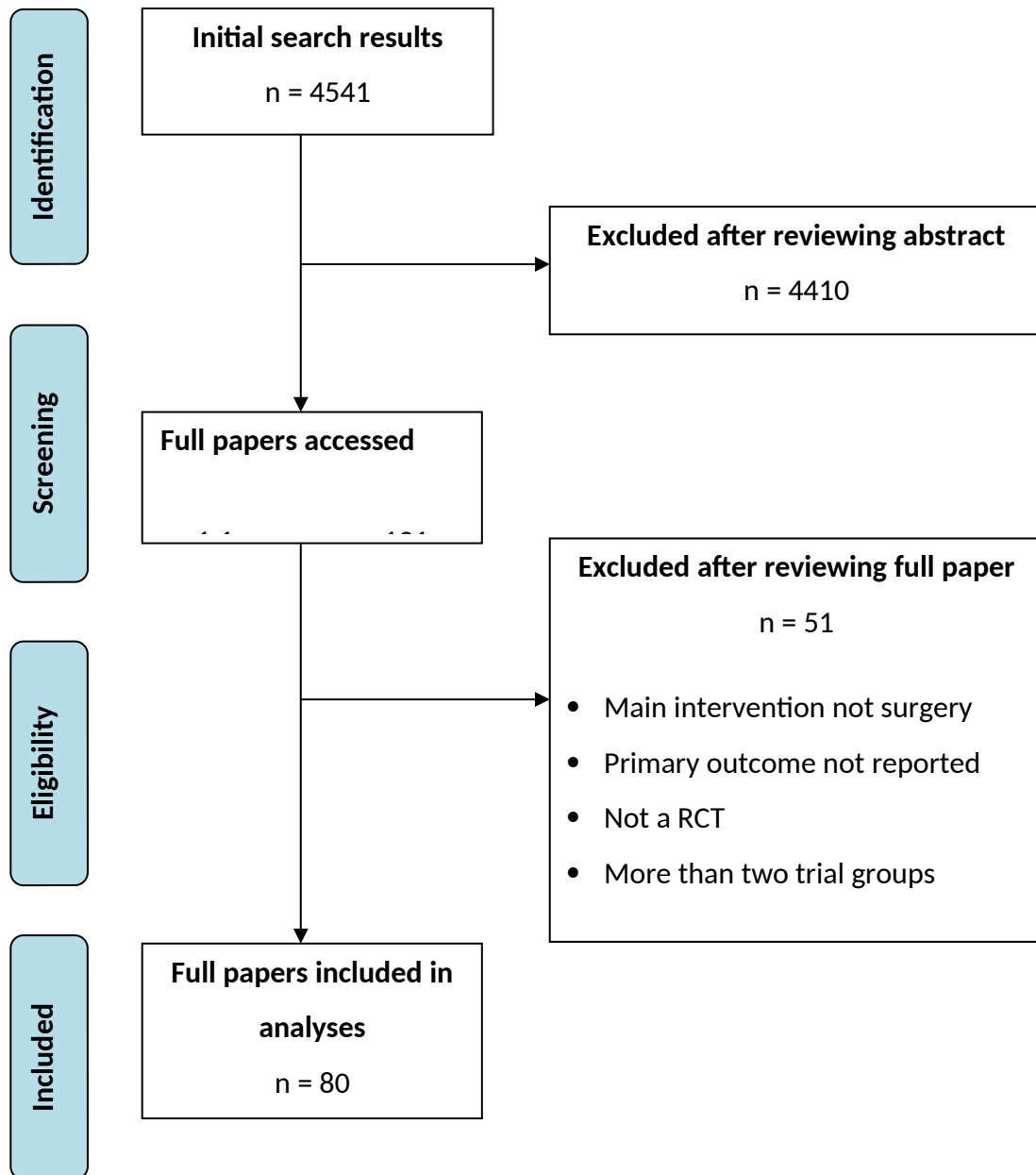
and those reading and interpreting study results can distinguish the interventions in each trial group and be certain that they were truly different from one another. Currently, however, this may be difficult to achieve and better methods for defining surgical interventions are needed in trial protocols in order to facilitate subsequent measurement of adherence to them during the trial, and for reporting details in the final paper.

This review involved an in-depth assessment of reporting standards relating to the intervention, and included studies from a wide range of surgical disciplines and journals; however, it has several limitations. The review used the main trial paper as the primary data source and trial protocols and other descriptions of interventions were only retrieved from those authors specifically mentioning a protocol within the trial report, meaning that some may have been missed. The study also did not examine reporting standards of concomitant interventions which is recommended by more recent guidance<sup>97</sup>. Finally, whilst every effort was made to scientifically categorise trials as predominantly pragmatic or explanatory, this was **subjective based on the opinion of two independent reviewers. It is possible that others may have classified them differently.** Many trialists may not have designed the trials with one design or another in mind (none of the included trial reports specifically reported their overall trial design as pragmatic or explanatory) and this is something that requires consideration within future RCTs in surgery.

This work has highlighted the need for further research to examine the way that surgical interventions are described, standardised and monitored within trial reports and protocols. CONSORT-NPT has conceded that the development of separate and specific guidance for reporting surgical interventions in RCTs is necessary. Consideration of such details should be initiated during trial design so that information can be provided within trial protocols. **The**

authors are currently developing a tool which provides guidance for surgeons and trialists to use during trial design to decide how to describe surgical interventions within trial protocols. It allows the constituent components and steps of interventions to be considered, and provides an approach for how standardisation and monitoring may be achieved. The use of this tool may help to reduce some of the criticisms of RCTs in surgery and facilitate the implementation of successful interventions in clinical practice. Whilst it may not solve all of the problems relating to the way in which surgical interventions are described and monitored in RCTs, it represents an important first step in this process. Further work is now required in order to test its applicability and usability within newly funded RCTs in surgery.

**Figure 1: PRISMA flow diagram of included studies<sup>98</sup>**



**Table 1: Criteria used to judge studies as predominantly explanatory or pragmatic**

<b>Criteria</b>	<b>Explanatory</b>	<b>Pragmatic</b>
<b>Number of centres</b>	Two or less	More than two
<b>Nature of primary endpoint</b>	Short term technical or clinical outcome	Patient-centred, long-term outcome
<b>Nature of analysis of the primary endpoint</b>	Analysis may be per-protocol or restricted to 'compliers'	Analysis includes all patients regardless of adherence (intention to treat)
<b>Type of follow up</b>	Multiple follow-up points, including the need for invasive investigations	Fewer follow-up points, no need for invasive investigations
<b>Inclusion/exclusion criteria</b>	Narrow inclusion criteria	Broad inclusion criteria

**Table 2: Reporting of intervention description and standardisation (items 4a and b)**

	<b>Interventions n = 160 (%)</b>
Intervention description	129 (80.6)
Reference to a previous article	43 (26.9)
Details of when intervention administered	29 (18.1)
Criteria for discontinuing intervention	7 (4.4)
Criteria for modifying intervention	39 (24.4)
Details of standardisation	47 (29.4)

**Table 3: Examples of papers describing ‘standardisation’ of interventions with no explanation (item 4b)**

Intervention type	Verbatim example
Surgical	‘All laparoscopically assisted and open colorectal resections were performed according to protocol guidelines.’ <sup>30</sup>
	‘All operations were performed in a standardised operative technique.’ <sup>52</sup>
	‘Both procedures were performed using standardised techniques.’ <sup>53</sup>
	‘There was no difference in the way that the axillary dissection was done in the two groups.’ <sup>21</sup>
	‘All interventions were standard straight laparoscopic resections.’ <sup>12</sup>
	‘Resections were performed according to the standard technique of optimal mesorectal excision.’ <sup>57</sup>
	‘Standard procedures for gastric resection and left colectomy were used at all participating centres.’ <sup>89</sup>
	‘The surgical procedures were standardised before initiation of the study and were performed in an identical manner across participating centres.’ <sup>14</sup>

**Table 4: Reporting of contextual factors (items 3 and 15)**

	<b>Publications (n=80)</b>
Number of centres performing the interventions:	
<i>Single</i>	26 (32.5)
<i>Multiple</i>	45 (56.3)
<i>Not reported</i>	9 (11.2)
If multicentre, number reported	44 (97.8)
If multicentre, countries reported	41 (91.1)
Types of included centre reported:	
<i>Yes</i>	21 (26.2)
<i>No</i>	52 (65.0)
<i>Unclear</i>	7 (8.8)
Usual caseload of centres provided:	
<i>Yes – for each participating centre</i>	0 (0)
<i>Yes – overall</i>	2 (2.6)
<i>Not reported</i>	78 (97.5)
Entry criteria to perform intervention provided	5 (6.2)
Any description of equipment required to perform intervention	60 (75.0)

**Table 5: Reporting of expertise (item 15)**

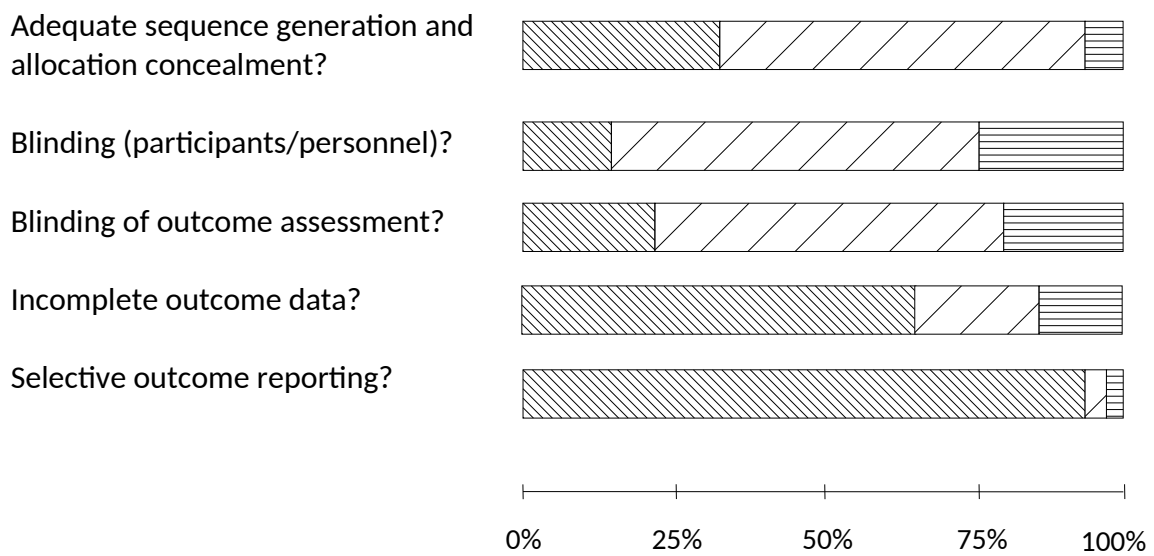
	<b>Interventions (n=160)</b>
Number of personnel performing intervention	39 (24.4)
Grade of personnel performing intervention	29 (18.1)
Usual caseload of personnel provided	4 (2.5)
Entry criteria to perform intervention provided	29 (18.1)
Learning curve mentioned	1 (0.6)
Mention of non-technical skills	0 (0)
Description of expertise of other team members required to deliver intervention	1 (0.6)



## Appendix 1: Top six medical and general surgical journals by impact factor<sup>8</sup>

Genre of journal	Journal	Impact Factor	Number of included articles
Medical	New England Journal of Medicine	53.486	14
	The Lancet	33.633	5
	Journal of the American Medical Association	30.011	7
	Annals of Internal Medicine	16.729	1
	PLOS Medicine	15.617	2
	British Medical Journal	13.471	2
<i>Total</i>			31
Surgical	Annals of Surgery	7.474	17
	Endoscopy	6.096	0
	Archives of Surgery	4.500	4
	British Journal of Surgery	4.444	25
	Journal of the American College of Surgeons	4.241	0
	Annals of Surgical Oncology	4.182	2
<i>Total</i>			48

## Appendix 2: Summary of Risk of Bias judgments across all studies



**Key:**



Low risk of bias



Unclear risk of bias



High risk of bias

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