

# Intervention Reporting Quality of Randomized Control Trials in Plastic Surgery

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## INTRODUCTION

With the increasing number of RCTs being conducted and published in plastic surgery, clear, accurate, and complete reporting of trial information is critical for readers to properly evaluate a trial's methodology and arrive at appropriate conclusions about its merits and applicability to patients. The Template for Intervention Description and Replication (TIDieR) checklist was introduced to address the limited guidance for reporting trial interventions.

## OBJECTIVES

In the present study, we will apply the TIDieR checklist to evaluate the completeness of intervention reporting of RCTs in plastic surgery and compare the quality of intervention reporting before and after the guideline was published.

## METHODS

A search was performed on PubMed to screen for plastic surgery RCTs. Authors screened 150 publications before January 2014 and 150 publications after January 2016 to give authors and journals time to adopt the TIDieR protocol and improve their reporting standards. The authors determined 130 trials to be RCTs and those trials were analyzed for TIDieR checklist components and baseline characteristics using a Google Form.

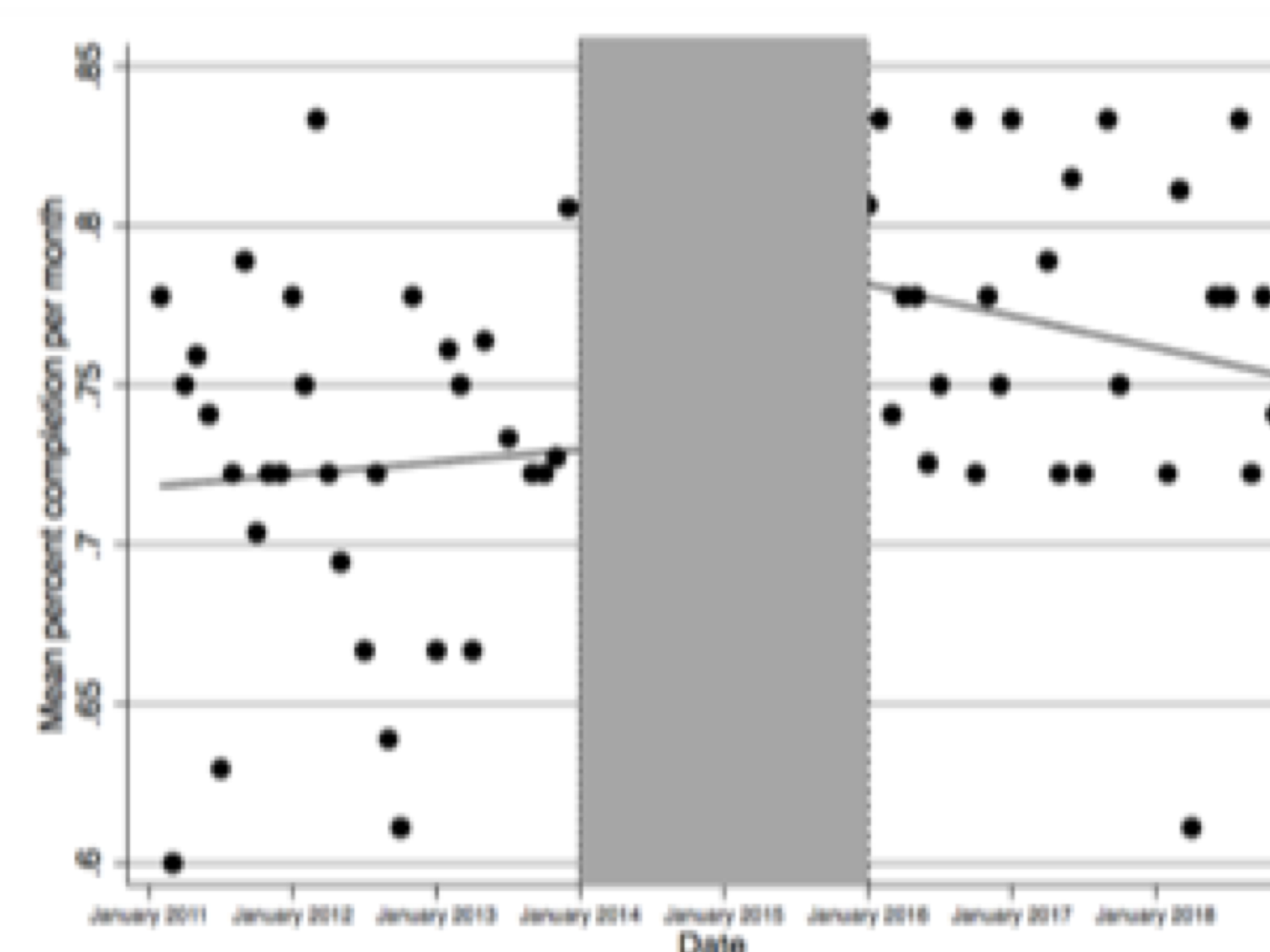


## CHARTS & FIGURES

TIDieR Checklist for Analyzed Plastic Surgery Articles

TIDieR Checklist		Variables
n=130		No. (%)
1. Do the authors provide the name or a phrase that describes the intervention?	Yes, complete	130 (100.0)
	Yes, incomplete	0 (0)
	No	0 (0)
2. Do the authors describe any rationale, theory, or goal of the elements essential to the intervention?	Yes, complete	130 (100.0)
	Yes, incomplete	0 (0)
	No	0 (0)
3. Materials: Do the authors describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of providers? Or, provide information on where the materials can be accessed (online appendix, URL, etc)?	Yes, complete	115 (88.5)
	Yes, incomplete	7 (5.4)
	No	8 (6.2)
4. Procedures: Do the authors describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities?	Yes, complete	125 (96.2)
	Yes, incomplete	4 (3.1)
	No	1 (0.8)
5. For each category of intervention provider (psychologist, nursing assistant, etc.), describe their expertise, background and any specific training given?	Yes, complete	25 (19.2)
	Yes, incomplete	48 (37.0)
	No	57 (43.8)
6. Do the authors describe the modes of delivery (face-to-face or by some mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group?	Yes, complete	130 (100.0)
	Yes, incomplete	0 (0)
	No	0 (0)
7. Do the authors describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Yes, complete	47 (36.2)
	Yes, incomplete	22 (16.9)
	No	61 (46.9)
8. Do the authors describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Yes, complete	129 (99.2)
	Yes, incomplete	1 (0.8)
	No	0 (0)
9. If the intervention was planned to be personalized, titrated or adapted, do the authors mention so and then describe what, why, when, and how?	Yes, complete	5 (3.8)
	Yes, incomplete	3 (2.3)
	No	1 (0.8)
	N/A	121 (93.1)
10. Do the authors mention if the intervention was modified during the course of the study, and if so, describe the changes (what, why, when, and how)?	Yes, complete	0 (0)
	Yes, incomplete	0 (0)
	No	130 (100.0)
11. Planned: If intervention adherence or fidelity was assessed, do they describe how and by whom, and if any strategies were used to maintain or improve fidelity, did the authors describe them?	Yes, complete	1 (0.8)
	Yes, incomplete	1 (0.8)
	No	0 (0)
	N/A	128 (98.5)
12. (If above answer was yes) Actual: If intervention adherence or fidelity was assessed, did the authors describe the extent to which the intervention was delivered as planned?	Yes, complete	1 (0.8)
	Yes, incomplete	0 (0)
	No	1 (0.8)
	N/A	128 (98.5)
Where was this information found?	Primary paper	130 (100.0)
	Online supplementary material	0 (0)
	Published protocol or previously published paper	0 (0)
	Website	0 (0)
	Other	0 (0)

TIDieR Compliance by Date



Generalized Estimating Equation Analysis

Characteristics (n=130)	Variables		
	IRR†	P-Value	[95% CI]
<b>Authors</b>			
<4 (n=28)	1	Reference	Reference
4-7 (n=77)	1.01	0.73	0.96-1.07
>7 (n=25)	1	0.884	0.95-1.06
<b>Funding</b>			
Industry or Private (n=25)	1	Reference	Reference
Public or mixed funding sources (n=24)	1.1	0.011	1.02-1.18
Not Mentioned (n=60)	1.08	0.015	1.02-1.15
No Funding (n=21)	1.1	0.004	1.03-1.18
<b>Participants</b>			
<60 (n=93)	1	Reference	Reference
60-70 (n=9)	0.97	0.19	0.92-1.02
71-280 (n=25)	0.9	0.257	0.76-1.08
>280 (n=3)	0.91	0.034	0.84-0.99
<b>Location</b>			
Not Mentioned (n=69)	1	Reference	Reference
US (n=18)	1.13	<0.001	1.09-1.18
Outside of US (n=43)	1.13	<0.001	1.07-1.20
<b>Hypothesis</b>			
Superiority (n=125)	1	Reference	Reference
All other hypotheses (n=5)	0.94	<0.001	0.91-0.96
<b>Study Design</b>			
Parallel arm (n=124)	1	Reference	Reference
Crossover or factorial (n=6)	0.99	0.406	0.95-1.02
<b>Intervention</b>			
Procedure (n=54)	1	Reference	Reference
Drug (n=53)	1	0.954	0.97-1.03
Device, mixed, or "other" (n=23)	0.99	0.777	0.94-1.05
<b>Blinding</b>			
No Blinding (n=52)	1	Reference	Reference
Blinding (n=78)	1.03	0.075	1.00-1.07
<b>Conducting Center</b>			
Single-Center (n= 111)	1	Reference	Reference
Multi-Center (n=19)	1.08	0.08	0.99-1.18
<b>CONSORT Endorsement</b>			
No (n=121)	1	Reference	Reference
Yes/Chart (n=9)	1.04	0.061	1.00-1.08
<b>TIDieR Endorsement</b>			
No (n=130)	1	Reference	Reference
Yes (n=0)	-	-	-
<b>Trial Registry</b>			
None (n=97)	1	Reference	Reference
Yes, listed (n=33)	1.05	<0.001	1.02-1.07

† IRR = Incidence rate ratio

## PRELIMINARY RESULTS

Plastic surgery journals adhered to the majority of TIDieR metrics. The areas of concern, however, include the location of intervention, experience and background of intervention providers, and assessment of fidelity. The proportion of pre-TIDieR metrics met was 0.7258 (CI 0.7093-0.7424) whereas the proportion of post-TIDieR metrics met was 0.7641 (CI 0.7421-0.7862).

## CONCLUSIONS

Overall, plastic surgery intervention reporting has areas of concern. Because we strive to further improve the quality of intervention reporting, we recommend that plastic surgery journals begin to adopt guidelines such as CONSORT and TIDieR, as research suggests that adoption of such guidelines improves quality of reporting and author adherence. Currently, only three of the nine included plastic surgery journals require authors to adhere to CONSORT guidelines and none currently require TIDieR adherence<sup>1,2,3</sup>. One additional solution is for leaders within plastic surgery to call for CONSORT to expand their requirements for intervention reporting to include vital items of the TIDieR checklist. We believe journal adoption of such guidelines could remedy the areas of concern and make plastic surgery trials the gold standard for quality intervention reporting.

## REFERENCES

<sup>1</sup>Instructions for Authors | JAMA Facial Plastic Surgery | JAMA Network. <https://jamanetwork.com/journals/jamafacialplasticsurgery/pages/instructions-for-authors>. Accessed July 16, 2019.  
<sup>2</sup>The Cleft Palate-Craniofacial Journal. SAGE Publications Inc. <https://us.sagepub.com/en-us/nam/the-cleft-palate-craniofacial-journal/journal203405>. Published March 21, 2017. Accessed July 16, 2019.  
<sup>3</sup>Elsevier. Guide for authors - Journal of Plastic, Reconstructive & Aesthetic Surgery - ISSN 1748-6815.