TRaiTS: Template for Reporting of Trials in Short format - swine examples

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Summary

A checklist for guiding authors in comprehensive reporting of swine individually or cluster-randomized controlled trials for journal abstracts or conference proceedings is shown. It is recommended that authors, conference organizers, and journal editors adopt this guideline to enhance study interpretation and use and reduce research wastage.

Keywords: swine, abstracts, conference proceedings, randomized controlled trials, reporting standards

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Resumen - TraiTS: Guía para la presentación de informes de estudios en formato corto - ejemplos para porcinos

Se muestra una lista de verificación para guiar a los autores para la presentación de informes de estudios aleatorios controlados en porcinos, individuales o por grupos, de resúmenes para revistas o memorias de congresos. Se recomienda que los autores, organizadores de conferencias y editores de revistas adopten esta guía para mejorar la interpretación y el uso de los estudios y reducir el desperdicio de investigación.

Résumé - TRaiTS: Gabarit de rapport d'essais en format court - exemples porcins

Une liste de vérification pour guider les auteurs lors de rapport complet d'essais contrôlés randomisés individuels ou regroupés sur le porc pour les résumés de revues ou les actes de conférence est présentée. Il est recommandé que les auteurs, les organisateurs de conférences et les éditeurs de revues adoptent cette directive pour améliorer l'interprétation et l'utilisation des études et réduire le gaspillage de la recherche.

It is important that an abbreviated study report, such as a journal abstract or conference proceeding, be as complete as possible within the word limit, as some decision-makers and practitioners may not have access to the complete study report depending on institutional subscription policies, finances, language of publication, etc. Further, some studies never have complete reports publicly available, and the conference proceeding is often the only publicly available description of the study.[1] Complete reporting in the abstract or conference proceeding also enables correct indexing in electronic databases[2] and aids in decision-making regarding inclusion into meta-analyses. However, word count limitations for abbreviated study reports can pose challenges in this respect.[2] The intent of this template of recommended items for reporting swine randomized controlled trials (RCTs) is to help meet this challenge. It is strongly recommended that students be taught complete reporting using this template and that seasoned researchers utilize the checklist as an efficient way to verify complete reporting. Swine journal editors and conference organizers should recommend this template as part of the submission guidelines and peer reviewers of swine RCTs should refer to the template when assessing submitted manuscripts.

Since various swine conferences have different word count limits for their study reports, the guidelines for the American Association of Swine Veterinarians veterinary student scholarships guidelines for abstracts have been used for illustrative purposes (550 words maximum, plus a visual aid [table or figure]; **https://www.aasv.org/annmtg/2019/studentseminar.htm**).

The items recommended for inclusion in a swine abstract or conference proceeding are listed in Table 1. Comprehensive reporting of clinical trials is challenging, a task made even more difficult by a short report length. Provided here is a streamlined list of factors that should be included in an abbreviated RCT report, with examples of how these items would be addressed in a short abstract format.

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This article is available online at **http://www.aasv.org/shap.html**.

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Table 1: Checklist for reporting randomized controlled trials in swine adapted for abbreviated study reports in journal abstracts or conference proceedings[2-7]

Item	Information to include
Title	Provide an informative title: Consider indicating the hypothesis tested, state if the study was randomized and the type of study design used eg, two-group parallel, multi-group parallel, crossover, factorial, superiority, equivalence, or noninferiority and whether experimental units were individually allocated or cluster-allocated.
Authors	For conference proceedings, the corresponding author and contact information should be listed, unless otherwise dictated by the author guidelines provided by the organizing body.
Introduction: Rationale	Provide a short rationale for the project and the design.
Introduction: Objective	Identify the objective(s) or hypothesis/es of the study. If there is more than one objective, identify which is the main objective (associated with the primary outcome of interest, which was used to determine the sample size). Also indicate the statistical hypothesis for the primary outcome (superiority, equivalence, or noninferiority). Only identify the key secondary objectives.
Methods: Study design	Indicate the allocation method (random or non-random), trial design (two-group parallel, multi-group parallel, crossover, or factorial), and experimental unit (pig, pen, barn, etc) and whether the study was individually allocated or cluster-allocated.
Methods: Participants	Report the stage of production, disease status of herd, study setting (type of swine production facility and country) and the eligibility criteria for the experimental unit such as pigs, litters, barns, or sites. If the experimental units are nested within housing units, ie, more than one site or barn, report the eligibly criteria for all housing units.
Methods: Interventions	Describe the interventions for each group, including generic name of compound, trade name (if applicable), name of manufacturer, dosage, duration, and route of administration, or procedure, as applicable.
Methods: Outcome	Define the main/primary outcome and describe when it was assessed (eg, the time frame over which it was measured). Only if space permits include key secondary outcomes of interest.
Methods: Allocation	Describe how the experimental units (pigs, pens, barns or sites) were allocated to the intervention group. If random allocation was employed, include the method used to generate the allocation sequence (eg, computer-generated, random-number table, etc), and indicate if the allocation sequence was concealed before eligibility was assessed (eg, via sealed envelopes or containers). If non-random methods were used (eg, systematic or alternation), state that non-random allocation was used. If individual allocation was done, indicate whether or not animals in different intervention groups were commingled.
Methods: Blinding	Indicate whether or not personnel applying treatments, caregivers, outcome assessors, or data analysts were blinded. Avoid non-specific terms such as “double-blinded” or “blinded” without specifying which tasks were blinded.
Methods: Analysis approach	Indicate the approach to analysis, both estimation of effect size and precision of the intervention and hypothesis-testing approach. Indicate if covariates were included and if clustering (a very common feature of livestock trials) was accounted for in the analysis. If hypothesis testing was used, discuss if adjustments for multiplicity were applied; if adjustments were applied, state the method used.
Results: Numbers allocated	Indicate the number of experimental units (pigs, pens, barns, sites, or herds) allocated to each intervention group. If nested with housing units indicate the number of housing units. If the study is still ongoing at the time of abstract submission, report the period of recruitment on which the data were based. Indicate age and/or weight of enrolled animals and stage of production of the enrolled animals.
Results: Recruitment	Indicate if the trial is still ongoing, closed to recruitment, or closed to follow-up. Indicate if the results and analysis presented are complete or preliminary.

Table 1: Continued

Item	Information to include
Results: Numbers analyzed	Report the number of experimental units (pigs, pens, barns, sites, or herds) per intervention group, used in the analysis.
Results: Outcome	For the primary outcome, report the results for each intervention group. This includes the number of experimental units with or without the event for dichotomous outcomes or the estimated mean and standard error for continuous outcomes for each intervention group. If the word limit permits, report the most critical subset of estimated effect sizes with a precision measure ie, a mean difference with confidence interval or SE, odds ratio with confidence interval or SE, or risk ratio with confidence interval or SE. Preferentially report estimates adjusted for pen (barn/site) effects if appropriate. For multi-group trials, report the most important pairwise comparisons. Give strong consideration to include a production outcome as a secondary outcome if not the primary outcome. Only if the word-limit permits include key secondary outcomes of interest in the same manner.
Results: Adverse events	Report the number of adverse events or side effects per intervention group.
Conclusions	Give a general interpretation of the results, clearly placing the findings in context for the veterinarian ie, how the results might be applied, including the uncertainty associated with unreplicated findings, sources of bias, and error. Place in context within the available body of work.
Animal use approval, registration, funding, conflicts of interest	List the source(s) of funding for the research, the animal use approval number, indicate if the trial was pre-registered and if the trial protocol is available, and declare conflicts of interest.

The adaptations made to the CONSORT and the REFLECT statement for abbreviated study reports, such as journal abstracts and conference proceedings, included using the term "experimental units" rather than "participants" to allow for studies that allocate interventions within pigs (limbs, eyes, hoofs, etc) and pen- or barn-level studies. "Blinding of participants" was removed as the pig participants in swine studies would not be expected to be aware of which intervention they received and eligibility criteria for owners or managers included since animals involved in the studies are incapable of consenting to participate in veterinary trials. Included here is information about the approach to analysis, in particular, reporting of adjustment for clustering. Grouping of experimental units within housing units such as pens, barns, or farms is a common feature of swine trials that is associated with within-cluster correlations that, if ignored, can lead to overestimation of the precision of estimates (ie, narrow confidence intervals and small standard errors). Authors should indicate if their trial protocol is available at a publicly accessible location such as Open Science, university digital depositaries, or the American Veterinary Medical Association clinical trials registry (**https://ebusiness.avma.org/aahsd/study_search.aspx**).

Deciding what to report can be difficult. Many studies have multiple outcomes, and it might not be feasible to report all outcomes and still provide adequate detail about the study design, approach to analysis, and study setting information. The interpretation of any result depends upon understanding the internal validity of the trial. Extrapolating those results to other populations relies on the external validity. Therefore, it is recommended that the focus be on ensuring end users have sufficient information to assess the validity of the primary outcome, rather than reporting multiple outcomes for which the validity cannot be assessed and for which the trials may not have been adequately powered. Anecdotally, this may present a shift away from prior approaches to reporting that focused on devoting space to results while sacrificing information about the methods that are necessary for the reader to assess validity. When word limits prevent the inclusion of factors related to validity and results for all outcomes evaluated, the primary outcome (ie, the outcome used to establish the sample size) should be reported in the results and discussion and the secondary outcome(s) dropped.

Another issue that may arise is reporting of contrast information for trials with three or more groups. As these trials have multiple possible comparisons and the space required to report all pairwise comparisons may not be available, authors should report each group outcome and standard error or confidence interval obtained from an appropriately adjusted model. Reporting these data enables end users to calculate any contrasts they are interested in. As it is frequently necessary to adjust for the effect of non-independence in swine studies that are conducted in populations with hierarchical structures such as litters, rooms, pens, and barns, providing the standard error enables calculation of all possible contrasts. If, as often happens, only the "raw" number of experimental units experiencing the outcome and the number allocated to each group is reported, the contrasts the reader is uniquely interested in cannot be correctly calculated. For pairwise contrasts, if reported at all, only the contrast(s) identified in the hypothesis should be reported.

An illustration of the reporting of individually randomized and cluster-randomized trials are presented separately, as each type of trial has different challenges for reporting.

Individually randomized trial template

The first example (Figure 1) demonstrates the suggested reporting style for a hypothetical individually multi-group randomized trial comparing the clinical efficacy of 3 hypothetical products (A, B, and C) in swine, with an accompanying visual aid (Table 2).

Cluster-randomized trial template

An example of comprehensive, transparent reporting of a hypothetical cluster-randomized (pen-level allocation) trial comparing the clinical efficacy of 3 different doses (multi-group) of a hypothetical feed additive (product A) in swine is illustrated by Comprehensive Reporting Example B (Figure 2 and Table 3). In this example, only one outcome is presented so that sufficient information about the analysis and clustering nature of the design could be included, which is more important for reaching appropriate inference and reducing research wastage.

Terms used

- A parallel trial is where the pigs are randomized to the intervention group and pigs remain in that same group throughout the study.
- A crossover trial is where pigs receive more than one intervention during the study, with a washout period between the interventions.
- In an individually randomized trial, the interventions are allocated to individual pigs.
- In a cluster-randomized trial, the interventions are allocated to entire groups of pigs.
- A trial evaluating a superiority hypothesis assesses if at least one group is better than another group concerning the outcome of interest.
- A trial evaluating a non-inferiority hypothesis assesses if at least one group is not worse than another group concerning the outcome of interest.
- A trial evaluating an equivalence hypothesis assesses if at least one group is equal to another group concerning the outcome of interest based on an a priori determined measure of equivalence.

Figure 1: Comprehensive Reporting Example A is an abbreviated report demonstrating recommended reporting of individually randomized, multi-group parallel controlled trials in swine for journal abstracts and conference proceedings. The superscript block capital letters indicate the checklist items from Table 1. Body of text word count ≤ 550 words.

TITLE **Comparing clinical cure rate for Product A, Product B, and Product C against hypothetical swine disease: An individually randomized multi-group parallel controlled trial**

AUTHORS J. A. Smith, J. B. Smith* word count = 550

*** Corresponding author: jbsmith@jbsmith.com**

INTRODUCTION: RATIONALE Hypothetical swine disease (HSD) is associated with high mortality and morbidity in late-nursery pigs. Products A, B, and C are registered for treatment of HSD, yet the comparative efficacy of these products is unclear. OBJECTIVES and HYPOTHESIS Our primary objective was to determine if the cure rate at Day 14 was higher for Products B or C compared to Product A on an endemic farm. The secondary objective compared weight gain after 14 days.

METHODS: TRIAL DESIGN PARTICIPANTS A 3-group, parallel, individually randomized trial was conducted on crossbred pigs at a commercial farm in Ontario, Canada. Eligible pigs had a rectal temperature > 39.9°C and had not received antimicrobial treatments for 2 weeks prior to enrollment. INTERVENTIONS Pigs received either Product A intramuscular (IM) at 7.5 mg/kg once, Product B subcutaneous at 3 mg/kg daily for 3 days, or Product C IM at 5 mg/kg twice, 48 hours apart. OUTCOME Day 0 was the day of diagnosis, enrolment, and first treatment. Weight gain and clinical cure were assessed on Day 14. Clinical cure was defined as rectal temperature < 40.0°C on Day 14. ALLOCATION Pigs were allocated to treatments using a random number generator. Treatment allocation was concealed from farm staff until eligibility assessment was complete. After allocation, all pigs were returned to their original pen, where treatment groups were mingled. BLINDING Farm staff could not be blinded to treatment group due to different administration routes. Although animals bore no indicators of the treatment received, caregivers were likely aware of intervention received. The veterinarian assessing clinical cure was unaware of treatment group. The data were coded as X, Y, or Z by group until statistical analyses were complete. ANALYSIS The statistical model was disease risk (logit link) or weight gain (linear link) across treatment groups (a fixed effect) with pen as a random effect. An adjusted risk ratio (OR) and 95% CI were calculated for all pairwise comparisons. We back calculated OR using the Product A baseline risk.

RESULTS: RECRUITMENT These results are preliminary because we will be repeating the study at a different site; however, for this site the data are complete and enrolment began October 15, 2017 and ended on November 30, 2017. NUMBERS RANDOMIZED, NUMBERS ANALYZED, ADVERSE EVENTS, OUTCOMES Table 2 presents the number of animals assessed for eligibly, enrolled, lost to follow-up, analyzed, baseline characteristics, clinical cure rate, and weight gain in each group on Day 14. RESULTS: OUTCOMES Adjusted relative risk for clinical cure and mean difference in weight gain are present in Table 2.

CONCLUSIONS In this preliminary analysis Product C had a higher clinical cure rate on Day 14 against HSD compared to Products A or B, as shown by the risk ratio greater than 1. The boundaries of the CI are consistent with a positive effect. These results suggest that veterinarians might employ Product C to treat HSD and have increased cures compared to Product A or B. Our findings are consistent with Jones et al, 2013 that Product C had a higher clinical cure than Product A in a random control trial (OR = 1.5; 95% CI, 0.9-1.9). Consistency of direction and magnitude of effect increases confidence in findings, as does the use of random allocation and blinding of outcome assessors.

TRIAL REGISTRATION The trial protocol was approved by the Primary Investigator's Institutional Animal Care committee but is not available. FUNDING and CONFLICT OF INTEREST This study was funded by the Superb Swine Association. Both authors are employees of Product C manufacturer.

Implications

The main take-away points for reporting RCTs in swine abstracts or conference proceedings are:

- Student researchers should be taught reporting using this template.
- Swine journal editors and conference organizers should encourage template use.
- Peer reviewers should consider using this template when assessing swine RCTs.

Acknowledgments

Conflict of interest

None reported.

Disclaimer

Scientific manuscripts published in the *Journal of Swine Health and Production* are peer reviewed. However, information on medications, feed, and management techniques may be specific to the research or commercial situation presented in the manuscript. It is the responsibility of the reader to use information responsibly and in accordance with the rules and regulations governing research or the practice of veterinary medicine in their country or region.

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Table 2: An example of how to present baseline data and results for an individually randomized multi-group parallel controlled trial in swine for journal abstracts and conference proceedings

EXAMPLE TABLE: Baseline characteristics at day 0 and results at day 14 for a randomized controlled trial comparing Products A, B, and C in late-nursery pigs

Pigs assessed for eligibility, No.	325		
Exclusion reason pre-enrollment			
Rectal temperature < 39.9°C, No. of pigs	12		
Received antimicrobials prior to enrollment, No. of pigs	11		
Pigs enrolled in the study, No.	**302**		
	Product A	**Product B**	**Product C**
Pigs allocated at enrollment (D 0), No.	98	104	100
Adverse events, No. of pigs	5	2	3
Injection site swelling	4	2	3
Anaphylaxis	1	0	0
Age, wk	10	10	10
Weight, mean (SD), kg	23 (3)	24 (4)	22 (4)
Female, No. (%)	49 (50%)	39 (38%)	73 (73%)
Results at D 14			
Complete data analyzed, No. of pigs	95	94	100
No. clinically cured	50 (52%)	75 (80%)	99 (99%)
Unadjusted mean weight (SE), kg/day	0.5 (0.1)	0.6 (0.1)	0.8 (0.1)
Pairwise Relative Risks	**Product A**	**Product B**	**Product C**
Product A	NA	1.5 (95% CI, 1.1-2.0),	1.9 (95% CI, 1.4-2.4),
Product B	NA	NA	0.89 (95% CI, 0.62-1.31).
Pairwise differences, kg/d	**Product A**	**Product B**	**Product C**
Mean difference from Product A	NA	0.04 (95% CI, -0.3 to 0.5)	0.3 (95% CI, -0.04 to 0.7)
Mean difference from Product B	NA	NA	0.2 (95% CI, -0.2 to 0.7)

Figure 2: Comprehensive reporting example B is an abbreviated report demonstrating recommended reporting of cluster-randomized, multi-group parallel controlled trials in swine for journal abstracts and conference proceedings. The superscript block capital letters indicate the checklist items from Table 1. Body of text word count ≤ 550 words.

TITLE **Comparing weight gain due to Product A feed additive in finishing swine: a cluster-randomized, multi-group parallel controlled trial.**

AUTHORS J. A. Smith, J. B. Smith* word count = 532

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INTRODUCTION: RATIONALE Product A is registered as a growth promotant in swine, but efficacy of different dosages has not been compared. OBJECTIVE The primary objective was to determine if weight gain would be higher in pigs that received 50 and 100 ppm in-feed of Product A compared to no Product A.

METHODS: TRIAL DESIGN, & PARTICIPANTS A 3-group, pen-randomized trial was conducted at 2 sites. Site was a block. Animals were housed in pens, nested within rooms, nested within a barn at each site. INTERVENTIONS Product A was administered at 0, 50, or 100 ppm in the basal diet from Day 0 (first arrival) to Day 21. OUTCOME The primary outcome was individual pig weight collected 30 days after the start of the feeding trial. ALLOCATION The research facility allowed allocation of different rations to pens. Two barns were used at each site. Each barn had 2 rooms. Each room had 50 pens, only 3 pens were used in the study. Farm staff filled both rooms of the barn with pigs as per usual farm practice over 2 to 4 days ie, pigs were not randomly allocated to pens. In each room the same 3 pens were randomly allocated to one treatment for each replicate. BLINDING Due to the distinctive aroma of Product A, caregivers were aware of pens receiving Product A but not the dose. Pen weight was an objective outcome. Data analysis was not blinded. ANALYSIS APPROACH We used a generalized linear model to estimate the final mean pig weight. The explanatory variable of interest was treatment group. Site and barn were included as fixed effects, while room and pen were included as random effects. Group-level results are reported as means (SEM) and comparisons as adjusted mean differences.

RESULTS: NUMBERS RANDOMIZED These results are final. RECRUITMENT The first group was enrolled on October 7-10, 2016 and the final group on March 8-11, 2019. NUMBERS ANALYZED, BASELINE CHARACERITICS The descriptive pen-level data, adjusted estimated group effect on final weight, the fixed effects, and random effects estimates are reported in Table 3. Eighty-five enrolled animals were not included in the analysis: 35 animals died and 50 animals from one pen were excluded because double the product was delivered for the first 6 days. Despite these losses, the data suggested that randomization was associated with balanced distribution of the arrival weight, and the analyzed populations were similar for arrival weight. OUTCOME There was no evidence of a difference in pig weight by treatment (Table 3). ADVERSE EVENTS No adverse effects were noticed.

CONCLUSIONS Evaluation of the estimates of the difference in mean weight per pig for the treatments are close to 0, suggesting no treatment effect. This result suggests that unless other evidence becomes available, there is little evidence to support the inclusion of Product A at 50 or 100 ppm to increase weight gain. We are unaware that others have conducted a similar evaluation, therefore this result is the only evidence available. Although we conducted the study in a cluster-randomized trial, the evidence to conclude no effect would be strengthened by other studies evaluating the same question.

TRIAL REGISTRATION The trial was approved by the Primary Investigator's Institutional Animal Care committee and is available at that Investigator's institutional digital repository (**www.PrimaryInvestiagtors.website.edu**).

FUNDING and CONFLICT OF INTEREST This study was funded by the Superb Swine Association. The authors declare that they have no conflict of interest.

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Table 3: An example of how to present baseline data and results for a pen-randomized, multi-group parallel controlled trial in swine for journal abstracts and conference proceedings

Baseline characteristics at D 0			
Total No of pigs eligible for enrollment	2400		
Total No. of pigs excluded at enrollment	0		
No. of site/No. of barns/No. of rooms/No. of pens enrolled in study	2/4/16/48		
No. of barns per site/No. of rooms per barn/No. of allocated pens per room	2/2/3		
No. of pigs enrolled per site/No. per barn/No. per room/No. per pen	1200/600/150/50		
Dosage of Product A	**0 ppm**	**50 ppm**	**100 ppm**
Pens allocated at enrollment	16	16	16
Pens lost to follow up	0	1	0
Pens included in analysis	16	15	16
Pigs allocated at enrollment	800	800	800
No. of pigs/pen enrolled, mean (SD)	50 (0)	50 (0)	50 (0)
No. pigs lost to follow-up (No. of pens)	16 (8)	58 (3)	11 (4)
Pigs included in the analysis	784	742	789
No. of individual pigs/pen in analysis, range	45-50	46-50	42-50
Individual pig weight at enrollment, mean (SD), kg	5.8 (0.89)	5.7 (0.89)	5.7 (0.89)
Results at D 30, kg			
Total final weight/pen, mean (SD)	950 (21.5)	894 (23.9)	928 (24.8)
Adjusted* individual pig weight, mean (SEM)	19 (0.13)	19 (0.14)	18.6 (0.13)
Pairwise differences in weight, kg	**0 ppm**	**50 ppm**	**100 ppm**
Mean difference (95% CI) from 0 ppm	NA	-0.1 (-0.46 to 0.1)	0.5 (0.1 to 0.8)
Mean difference (95% CI) from 50 ppm	NA	NA	0.5 (-0.17 to 0.91)

* Variance components: Model = final weight ~ 0 + treatment + site + nursery + (random effects for pen [room]) + error

Fixed effects: Site (N = 2, Estimate: 0.6228, Confidence Interval: [-0.362, 1.615]), Barn (N = 4, Estimate: 0.6228, -0.4919, Confidence Interval: [0.5493, 1.134],[0.5397 ,-0.911]),

Random effects: Room (N = 16, Variance: 12.32, ICC: 0.204), Pen (N = 48, Variance: 2.64, ICC: 0.0438), Residual (N = 2350, Variance: 60.3302)

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