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Spencer-Bonilla, G.; Branda, M.E.; Kunneman, M.; Bellolio, F.; Burnett, B.; Guyatt, G.; ... ; Shared Decision-Making Atrial Fibr

Journal of Clinical Epidemiology 152 (2022) 185−192

Journal of Clinical Epidemiology

ORIGINAL ARTICLE

Encounter-based randomization did not result in contamination in a shared decision-making trial: a secondary analysis

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Accepted 30 September 2022; Published online 8 October 2022

Abstract

Objectives: To estimate the level of contamination in an encounter-randomized trial evaluating a shared decision-making (SDM) tool.

Study Design and Setting: We assessed contamination at three levels: (1) tool contamination (whether the tool was physically present in the usual care encounter), (2) functional contamination (whether components of the SDM tool were recreated in the usual care encounters without directly accessing the tool), and (3) learned contamination (whether clinicians "got better at SDM" in the usual care encounters as assessed by the OPTION-12 score). For functional and learned contamination, the interaction with the number of exposures to the tool was assessed.

Results: We recorded and analyzed 830 of 922 randomized encounters. Of the 411 recorded encounters randomized to usual care, the SDM tool was used in nine (2.2%) encounters. Clinicians discussed at least one patient-important issue in 377 usual care encounters (92%) and the risk of stroke in 214 encounters (52%). We found no significant interaction between number of times the SDM tool was used and subsequent functional or learned contamination.

Conclusion: Despite randomly assigning clinicians to use an SDM tool in some and not other encounters, we found no evidence of contamination in usual care encounters.

Keywords: Contamination; Complex health interventions; Randomized trials; Shared decision-making; Decision aid; Atrial fibrillation

1. Introduction

When designing randomized trials of complex interventions such as shared decision-making (SDM), investigators need to optimize both applicability and feasibility. Contamination refers to access to the intervention by participants randomized to the control group. Because investigators and their audiences are generally interested in the impact of an intervention when application of that intervention is restricted to the intervention group, and control group access to the intervention will therefore lead to underestimation of the effect of a truly useful intervention, substantial

Funding: The trial was funded by and conducted independently of the National Heart, Lung, and Blood Institute (NHLBI) of the U.S. National Institutes of Health (RO1 HL131535-01). The funding body had no influence on the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Declarations of interests: The authors declare that they have no competing interests.

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https://doi.org/10.1016/j.jclinepi.2022.09.017
0895-4356/

What is new?

Key findings

- In this secondary analysis of an encounter-randomized trial of a shared decision-making tool regarding anticoagulation to reduce the risk of stroke for patients with nonvalvular atrial fibrillation, we found no compelling evidence of significant contamination in usual care encounters.

What this adds to what is known?

- Empiric data addressing the risk of bias secondary to contamination in complex interventions are sparse.
- In this study of a large, encounter-randomized trial with more than 800 recorded encounters, three levels of contamination were examined.

What is the implication, what should change now?

- Investigators and reviewers are often concerned about the risk of contamination in encounter-randomized or individual-randomized trials testing complex interventions and may employ more costly or resource-intensive methods, such as cluster-randomization to minimize contamination.
- After considering the context, risks, benefits, and practical implications of their intervention, investigators may use the findings of this analysis to better estimate the risk of bias that contamination may cause as they select the level of randomization.

contamination undermines the applicability of study results. The amount of contamination that occurs however has not been well characterized.

In any study in which contamination is an issue, it would be useful to estimate the magnitude of the problem. Because a large degree of contamination may be responsible for failure to demonstrate a treatment effect that indeed exists, this is particularly true in ''negative'' studies. The issue has arisen in the context of the SDM trials performed in our research unit in which an SDM tool is introduced into the medical encounter to support conversations between clinicians and patients regarding a medical decision. The randomized trial discussed here tested an interactive online tool to support clinical conversations regarding starting, stopping, or continuing anticoagulation with patients with nonvalvular atrial fibrillation (AF) [1].

To test the impact of this SDM tool, the investigators could randomize at the encounter, clinician (patients nested within clinicians), or at the clinic level (clinicians and patients nested within a practice). The clinic and clinician levels are examples of clustered randomizations. A key advantage of clustering—that is, the implementation of the intervention within these units—is that it allows for training of clinicians allocated to using the SDM tool but not those allocated to control. Cluster-randomization minimizes the risk of contamination but requires access to sufficient clusters and increases the number of participants needed to achieve statistical power, typically by about 50% [2]. This is because of clustering, by which the similarity or difference within cluster impacts the amount of variation around the estimates of outcomes. Such clustering effect needs to be accounted for in more complex statistical analysis than other study designs [3]. Cluster-randomization may also increase the risk of prognostic imbalance when clusters are randomized prior to completion of recruitment of participants, potentially losing allocation concealment [4,5]. Had this trial been cluster-randomized, for example, clinicians with more experience with SDM may have been more likely to participate in the study at a site randomized to the intervention.

In a clinician-randomized trial, that is, when clinicians constitute the clusters, individual clinicians are randomized to either use of the tool or usual care throughout the duration of the trial. This approach could result in reduced participation by clinicians disappointed by their assigned intervention/arm which could compromise the feasibility of the study. In addition, if decisions regarding patient participation were in the hands of the clinicians, and allocation to intervention and control groups influenced clinician decisions to enroll patients in the trial, clinician clusters could compromise prognostic balance in patients [6].

An alternative to cluster randomization is to randomize each clinical encounter. In an encounter-randomized trial, each clinical encounter (patient-clinician dyad) is randomized to usual care with or without use of the SDM tool. With this approach, the same clinician uses the SDM tool in some encounters but not in others. The most significant downside of encounter-level randomization is the potential for contamination, in part because of the need to train and provide access to the intervention to all participating clinicians which may lead to a learning effect.

In our SDM4Afib trial [1], the research team and the trial Data Monitoring Committee performed randomization at the encounter level. We now report a secondary analysis to estimate the presence and magnitude of contamination in this encounter-randomized trial.

2. Materials and methods

We conducted a secondary analysis of a multicenter, encounter-level, randomized trial enrolling patients with nonvalvular AF who were considering starting or continuing anticoagulation to prevent thromboembolic strokes. The study protocol and the primary results are published [1,7−9]. The trial took place within five health

systems including academic medical centers (Mayo Clinic, the University of Alabama at Birmingham, and the University of Mississippi Medical Center), a suburban group practice (Park Nicollet Health Partners), and an urban safety-net health system (Hennepin Health) in Minnesota. Clinicians at the participating sites who routinely had conversations about anticoagulant treatment with patients with AF were eligible for participation. Eligible clinicians were invited to participate in the trial via e-mail or during established clinic meetings.

After agreeing to participate, the clinicians took part in brief training sessions, either individually or in groups. In training sessions, through role playing with the clinician, study staff demonstrated how to use the anticoagulation choice SDM tool [1], an online and within-encounter conversation aid. The tool offers three main components: (1) risk prediction, (2) risk modification with anticoagulant use, and (3) description of patient-important issues of available anticoagulant treatment options (direct oral anticoagulants and warfarin) (https://anticoagulationdecisionaid.mayoclinic.org/). In addition, when feasible, clinicians viewed a prerecorded video demonstration. These training sessions were scheduled either during times when the clinicians did not have clinical duties or took place ''just in time'' prior to appointments with eligible patients. Clinicians received the online link to the tool during the training and this link remained accessible for the duration of the trial.

When an eligible patient agreed to participation in the trial, the encounter underwent computer-generated randomization and clinicians were instructed to incorporate the anticoagulation choice SDM tool to the clinical encounter or continue usual care alone [7]. When allocated to usual care, clinicians were instructed not to access the SDM tool. Clinicians who participated in the trial for multiple encounters sometimes used the tool and other times did not, depending on whether the encounter was randomized to usual care or use of the SDM tool.

Data collection included medical record review, postencounter participant surveys, and encounter observations. With the consent of patients and clinicians, we recorded each clinical encounter with audio and video or audio alone. Although only those encounters which were recorded were evaluable, patients and clinicians could participate in the trial and decline encounter recording. The recordings were independently coded by two reviewers on outcomes of interest until agreement was obtained. We used the validated OPTION-12 scale to code clinicians' behaviors to involve patients in decision-making. The OPTION score ranges from 0 to 100, with a higher score indicating more behaviors to involve patients [10]. In addition, we used a self-developed checklist to code fidelity of whether and how the tool was used. For example, we coded which elements of the tool were used (risk calculator and/or issues of importance to patients), whether and how risks were discussed (mentioning reference class, both positive and negative framing, and time horizon), whether stochastic uncertainty was discussed (e.g., ''I don't know if you are one of the 10 or one of the 90''). Using the recordings, we assessed contamination at three levels:

1. Tool contamination: Was the SDM tool accessed in control encounters?
   a. Measurement: All encounters with a recording were evaluated for tool use in both the intervention and usual care encounters.
2. Functional contamination: Were components of the SDM tool recreated without directly accessing the SDM tool in control encounters?
   a. Measurement: We assessed fidelity items that identified whether components of the tool were being used within the encounter and were indicated as present or not for each encounter with a recording in both intervention and usual care encounters.
3. Learned contamination: Did clinicians ''get better at SDM'' in the control encounters as they accrued more experience using the SDM tool in intervention encounters?
   a. Measurement: The OPTION-12 score was calculated for all encounters with a recording in both intervention and usual care encounters.

2.1. Statistical analysis

We used descriptive statistics to characterize the encounters and the presence of tool, functional contamination, and learned contamination. To evaluate functional and learned contamination, we used a mixed model adjusting for arm, encounter order (i.e., first enrolled encounter for clinician, second enrolled encounter for clinician, etc.) with the interaction of order and arm as fixed effects and clinician as the random effect. Concordance between raters was evaluated using Lin's agreement (chance-adjusted inter-rater reliability). We tested the significance of the interaction term using a chi-squared test statistic. Two-sided P value < 0.05 was considered significant. All analyses were conducted in SAS version 9.4 (Cary, North Carolina).

3. Results

Of the 922 evaluable encounters, 830 had video recordings (419 interventions and 411 controls) (Table 1). Within these encounters there were 139 clinicians with eligible encounters with a median of 2 encounters per clinician (interquartile range 1−6, range 1−65). Chance-adjusted inter-rater reliability (Lin's agreement) was 0.8 for the OPTION-12 score and $\kappa > 0.8$ across individual fidelity items.

3.1. Tool contamination

Of the 411 recorded usual care encounters, the SDM tool was used by 5 (3.6%) of the 139 clinicians in 9 (2.2%) encounters. Of the five clinicians who used the tool in an encounter allocated to usual care, one used the tool within the first enrolled encounter and the remaining four clinicians had a median of eight encounters prior to the encounter in which they used the tool in a usual encounter (range 3, 28).

In all nine of these encounters, the clinician presented the tool to aid in the decision-making process rather than as a reference for themselves or as a website that patients could refer to after the encounter. The risk calculator was used for current risk in all nine encounters, future risk in eight encounters, and the part of the tool that discusses individual issues (e.g., cost, medication routine) in seven encounters. The patient and clinician chose to discuss the issues of greatest salience in 3 (33%) encounters and the clinician reviewed all of issues in the SDM tool in 3 (33%) encounters.

3.2. Functional contamination

Clinicians discussed risk of stroke in more than half of the 411 usual care encounters (214 encounters; 52%) compared to 96% of encounters in the SDM tool arm and the risk horizon in 33% of the usual care encounters (136 encounters) compared to 80% of encounters in the SDM tool arm. In most usual care encounters (377 encounters; 92%), clinicians discussed at least one patient-important issue regarding anticoagulation. Table 2 shows the rates of other components of functional contamination. Figure 1 shows the rate of presence of these components over time as measured by the number of exposures to the SDM tool (encounters in which they were randomized to use of the tool) prior to the measurement. No significant change in functional contamination was observed after repeated exposures to the SDM tool.

3.3. Learned contamination

There were no significant differences in the rates at which clinicians fostered choice awareness, offered treatment options, nor were there differences in patient engagement between the two groups (Table 2). OPTION-12 scores were significantly higher in the SDM tool arm than in the usual care arm (33 [SD 11] vs. 29 [SD 13]) but we found no significant interaction in OPTION-12 scores between trial arm (SDM tool vs. usual care) and the clinician's experience with using the SDM tool in the trial ($P = 0.99$) (Fig. 2).

4. Discussion

4.1. Summary of findings

We assessed the rate of three levels of contamination in a randomized trial testing a complex intervention, an SDM tool to support discussion regarding anticoagulation in patients with nonvalvular AF. We found low rates of tool contamination; clinicians used the SDM tool in only nine of 499 usual care encounters. We found high rates of possible functional contamination, particularly in the domain of mentioning patient issues and describing the risk of stroke. This did not, however, increase with a higher number of exposures to the tool, suggesting the likelihood that the behaviors were part of clinicians' usual SDM prior to the trial. Similarly, we did not find evidence of learned contamination over time; the number of prior exposures to the SDM tool was not associated with increased scores in OPTION-12 or other measures of effective SDM.

4.2. Limitations

Our study findings should be interpreted in the context of several limitations. All clinicians received training in the use of the SDM tool prior to their first encounter. We did not observe encounters prior to this training. It is possible that this first exposure to the SDM tool (during training) may have primed the clinicians to incorporate more components of SDM in the usual care arm. In other words, maximum (and possibly substantial) learning from the SDM tool occurred on first exposure to the tool and thus further exposure failed to result in further learning and further modification with exposure. Ruling out this possibility would have required an assessment of clinician behavior prior to their education regarding the SDM tool, assessments that we did not carry out.

Table 1. Enrollment

Trial characteristics	Encounters	Encounters with recordings
Patients enrolled, *N*	922	830
Clinicians with patients enrolled, *N*	151	139
Encounters per clinician: Median (IQR), Range	2 (1, 6), 1–74	2 (1, 6), 1–65
Clinicians with at least one intervention encounter, *N*	109	99
Median # of intervention encounters (IQR), Range	2 (1, 4), 1–42	2 (1, 5), 1–36
Clinicians with at least one usual care encounter, *N*	110	102
Median # of usual care encounters (IQR), Range	2 (1, 4), 1–38	1 (1, 4), 1–36

Table 2. Assessment of levels of contamination

Level of contamination	SDM tool (*N* = 419)	Usual care (*N* = 411)
Level 1: Tool Contamination		
Use of Tool in Encounter	401 (95.7%)	9 (2.2%)
Level 2: Functional Contamination		
Description of risk of stroke	403 (96%)	214 (52%)
Description of risk in both positive and negative	238 (57%)	11 (3%)
Describe the reference class for the risk of stroke	194 (46%)	18 (4%)
Describe the time horizon for risk of stroke	336 (80%)	136 (33%)
Mention 'Stochastic uncertainty'	26 (6%)	6 (1%)
Describe the risk reduction	392 (94%)	116 (28%)
Describe the time horizon for the stroke risk reduction	133 (32%)	16 (4%)
At least one patient issue was mentioned	405 (97%)	377 (92%)
Level 3: Learning Contamination		
Patient engaged—Participating, *n* (%)		
Participating	200 (48%)	215 (52%)
Partially, minimum engagement	200 (48%)	167 (41%)
No, Patient detached	19 (5%)	29 (7%)
Fostered Choice awareness, *n* (%)		
Yes, w/out recommending	307 (73%)	245 (60%)
Yes, w/recommending	85 (20%)	61 (15%)
No, w/implied options	10 (2%)	25 (6%)
No	17 (4%)	80 (19%)
Options of treatment offered, *n* (%)		
All four options	6 (1%)	10 (2%)
Warfarin, DOAC, No Rx	24 (6%)	6 (1%)
Warfarin, DOAC, Aspirin	52 (12%)	56 (14%)
Warfarin, DOAC	314 (75%)	243 (59%)
Warfarin & Aspirin or DOAC & Aspirin	1 (0%)	5 (1%)
One option of either Warfarin, DOAC, or Aspirin	16 (4%)	66 (16%)
No options	6 (1%)	22 (5%)
OPTION-12 Scale, mean (SD)	33 (11)	29 (13)

4.3. Findings in context

Investigators and reviewers are often concerned about the risk of contamination in randomized trials testing complex interventions. Investigators may employ more costly or resource-intensive methods, such as cluster-randomization and intensive monitoring to assess for and minimize contamination. Empiric data addressing the risk of bias secondary to contamination in complex interventions are sparse.

Craven et al. conducted an analysis to identify possible contamination in a randomized trial testing a positive feedback-based intervention for students [11]. They randomized students within a classroom to receive either the intervention or usual education and evaluated a separate control classroom. They found evidence of contamination: students randomized to the control group within the classroom had higher scores than those in the external classroom. The investigators attributed this contamination to low fidelity to the intervention by the teachers with students randomized within their classrooms. Teachers described having low self-rated fidelity because they found it difficult to praise only some students within one classroom; external observer assessment correlated with teachers' self-assessments [11]. This design differs from the present trial in that use of the SDM tool did not occur in front of patients randomized to usual care encounters.

In a scoping review of complex interventions in mental health including 234 randomized trials, Magill et al. found that only a minority of trial publications included attempts to quantify contamination [12]. In these trials, the risk of contamination, defined as the binary receipt of the treatment in the control arm, was 13% (interquartile range 5%–33%), higher than our rate of tool contamination of 2%. Magill et al. found that, to minimize contamination, among other methods, investigators used cluster randomization at the clinician level to ensure that clinicians only delivered one of the interventions. They identified four trials that used both cluster and individual randomization [13–16]. In these trials, for about half of the outcomes, there were nonsignificantly smaller treatment effects in the individual-randomized arms [12]. Gilbody et al. analyzed 34 randomized trials testing

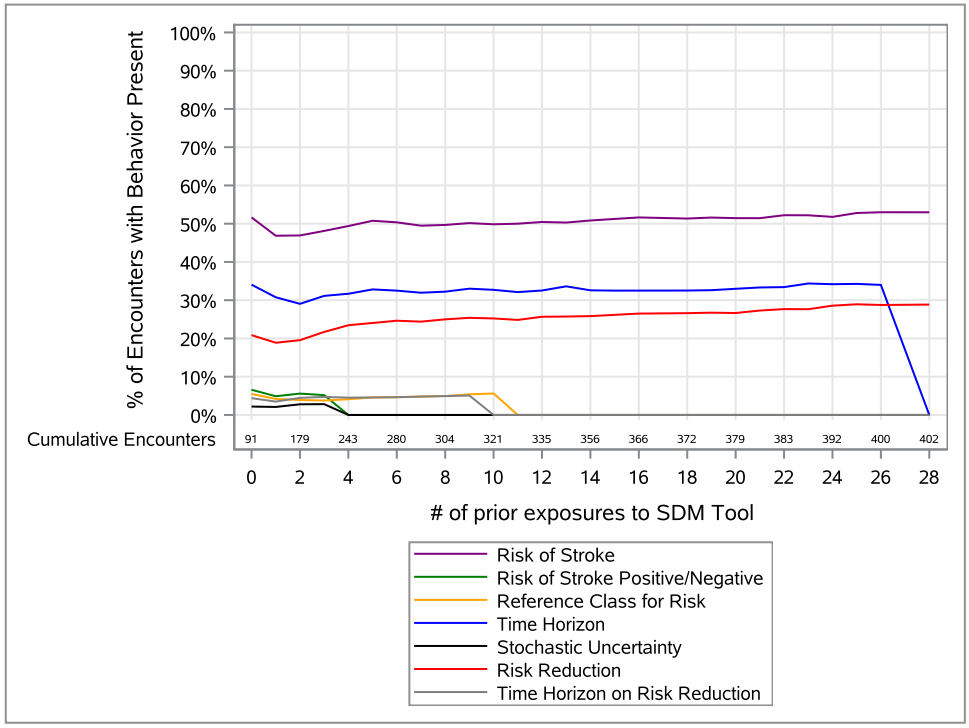

Fig. 1. Functional contamination for usual care encounters after exposure to the SDM tool.

collaborative care for depression, a form of care in which a case manager and a primary care clinician collaborate to improve the quality of care for depression [17]. The authors found no difference in baseline characteristics or effect size between the 14 cluster-randomized and the 20 individually randomized trials, although individually randomized trials yielded more heterogeneous results. They also found that statistical adjustment with the intraclass correlation coefficient in cluster-randomized trials had a minimal effect on the estimate of effect [17]. In addition, in simulations, investigators have estimated that at expected rates of contamination of less than 30%, individual allocation maintains a sample size advantage over cluster randomization [2].

The risk of contamination may be context-dependent. Simulations using data from a prostate cancer screening trial showed a significant contamination due to prostate cancer screening being an established practice in the community and proposed that this may have decreased the ability of investigators to detect a mortality benefit from screening (because of significant screening in the control arm) [18]. Similarly, when breast cancer screening with mammography became popular in the community, investigators examining contamination rates in a breast cancer screening trial noted appreciable rates of screening mammograms in the control group [19]. Therefore, temporal trends and society recommendations and guidelines may impact the frequency with which control patients receive the intervention. This concern, which can be thought of as the "background noise, where the treatment already existed to some extent within the healthcare system" was uncommonly addressed in the trials identified by Magill et al. [12]. Prior to our commencing enrollment in our randomized trial in 2014, three major cardiovascular medicine organizations issued a Class I recommendation for clinicians to implement SDM in the treatment of patients with nonvalvular AF [20]. Given this recommendation, clinicians may have been more motivated to practice SDM, even in encounters allocated to usual care. Even prior to the guideline recommendations, clinicians may have used online calculators to estimate the risk of stroke and bleed prior to starting anticoagulation which likely contributed to the "functional contamination" which consisted largely of clinicians estimating and sharing with the patient their estimated risk of stroke.

Overall, the magnitude of the risk of contamination between cluster-randomized and individual-randomized trials remains poorly characterized and there is little evidence to support larger treatment effects in cluster-randomized trials. In addition, given that clinicians tend to have low rates of uptake of SDM tools, and complex interventions are difficult to implement, it may be that concern regarding contamination is greater than necessary [21,22].

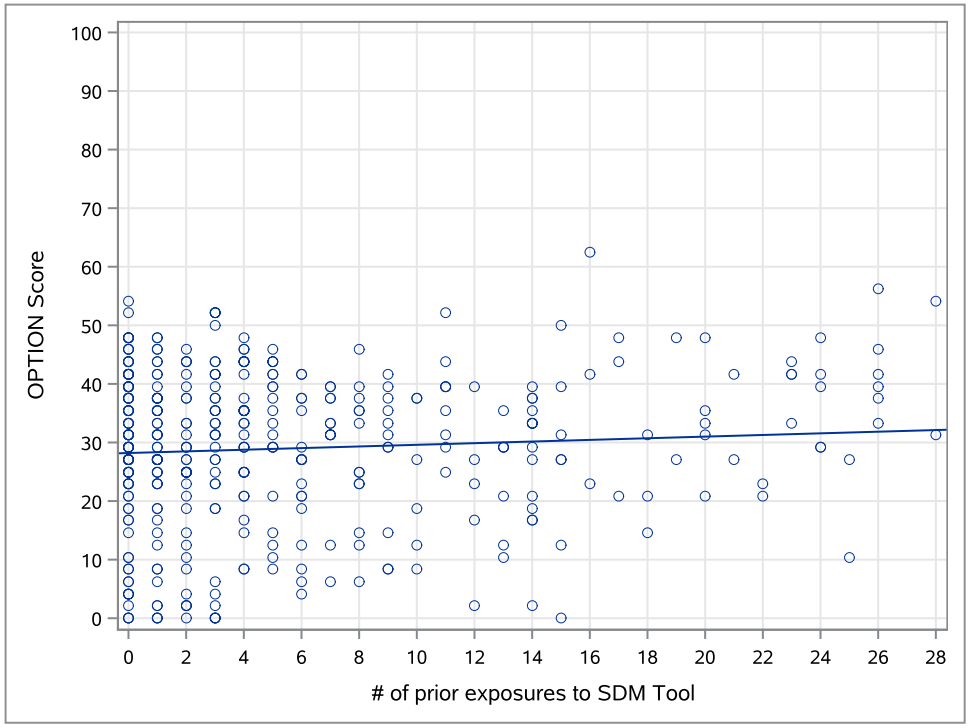

Fig. 2. Learned contamination of OPTION-12 for usual care encounters after exposure to the SDM tool.

5. Conclusion

In this secondary analysis of an encounter-randomized trial testing the effect of an SDM tool, we found low rates of tool contamination and no interaction effect between the number of exposures to the SDM tool and functional or learned contamination. After considering the context, weighing the risks, benefits, and practical implications, investigators may use these findings to better estimate the risk of bias that contamination may cause while selecting the preferred level of randomization. A thorough assessment and analysis of different levels of possible contamination as was described here may, nevertheless, help investigators and readers critically appraise the trustworthiness of results of trials testing complex interventions that, by design, may be put at an appreciable risk of contamination.

CRediT authorship contribution statement

Gabriela Spencer-Bonilla: Conceptualization, methodology, investigation, and writing. Megan E. Branda: Conceptualization, methodology, formal analysis, writing, data curation, funding acquisition. Marleen Kunneman: Conceptualization, investigation, writing, funding acquisition. Fernanda Bellolio: Conceptualization, investigation, and writing. Bruce Burnett: Conceptualization, investigation, and writing. Gordon Guyatt: Conceptualization, methodology, formal analysis, and writing. Victor M. Montori: Conceptualization, methodology, formal analysis, investigation, writing, funding acquisition.

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Data safety and monitoring board

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Expert advisory panel

Paul Daniels, Bernard Gersh, Erik Hess, Thomas Jaeger, Robert McBane, and Peter Noseworthy (chair).

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