

Decision for round #1 : *Revision needed*

Decision on your Stage 2 Registered Report: Revisions Required

Dear Dr. Hugo Najberg,

Thank you for submitting your Stage 2 Registered Report, entitled "Sugary Drinks Devaluation with Response Training Helps Early Diet Adherence Failures", to PCI RR. Two reviewers who have reviewed the Stage 1 RR previously have now reviewed your manuscript. I too have independently read your paper before consulting their comments. As you will see, the reviewers' assessment is overall positive, but they have also provided some critical feedback which I believe will further strengthen your manuscript. I would therefore like to invite you to submit a revised manuscript, to address the reviewers' comments.

Thank you for your positive review of our work and the constructive comments. We have addressed each point in blue and updated the manuscript to reflect them (changes in the manuscript also in blue).

1- As both reviewers pointed out, one major issue with the current manuscript is that the interpretation of the results gives too much weight to an exploratory result. It is certainly fine to report results of exploratory analyses in a registered report, as long as they are clearly labeled as exploratory. However, the main conclusions should then still be based on the pre-registered, confirmatory analyses. Right now, both the title and the abstract focus very much on the exploratory result, which is problematic. These parts need to be revised to accurately reflect the main conclusions from the pre-registered analyses.

We thank you for this general comment. We emphasized our exploratory results because it became an important new message of the paper after we realized that our design choice (i.e. to compare a 50% association group with a 100% association group) lead to inconclusive results on the main hypothesis (i.e. the absolute effect of response training on diet). However, we recognize that we should better adhere to the philosophy of Registered Reports (RR), ensuring that the main message remains consistent with the initially planned analysis, even if the results are inconclusive.

We have now reduced the weight of the exploratory results on our main conclusion, and it is now reflected in the title, the abstract and the discussion section of the manuscript. As an example, the Conclusions sub-section now reads p.21: "The current registered report concludes that seven to twenty days of combined practice of a Go/NoGo and cue-approach 100% mapping training does not improve restrictive dieting maintenance in healthy participants when compared to a control group with 50% mapping, but exploratory results hint that it could still benefit at-risks population".

2- Related, the main conclusion on page 18 is that "The current registered report cannot conclude on whether seven to twenty days of combined practice of a Go/NoGo and cue-approach 100% mapping training improve restrictive dieting maintenance in healthy participants when compared to a control group with 50% mapping." However, the statistical evidence for the primary hypothesis (i.e., H1) is clear - there is no significant difference between the experimental and the

control group in the number of successful days of diet. Thus, the main conclusion also seems clear - the combined GNG and CAT did not improve restrictive dieting maintenance compared to a 50% mapping control group. Of course, the result might be different if a different control training had been used, or if a different sample had been recruited. However, it is important to note that these explanations are post hoc (i.e., the control training and the sample seemed fine at Stage 1). Furthermore, these are potential explanations for why you did not observe an effect for H1 here. Thus, the main conclusion is still that there is no effect for H1, rather than that no conclusion can be drawn. In general, I think the null findings can be highlighted more in the general discussion (e.g., by linking these to some null findings in the previous literature), and more importantly, the main conclusions should be about the (null) findings from the pre-registered analyses.

We totally agree and have now clarified this point. We stress more the null finding of the primary hypothesis in the Discussion section to reflect its confirmatory nature. The argument made on the interpretation for dieting behavior is clarified and now separated from the rest. We have split our arguments to better distinguish i) the incapacity of the study's design to conclude on the absence of absolute effect in case of null results, ii) the interpretation of the primary hypothesis' null results, and iii) exploratory results.

To summarize, in the Discussion (sub-section now titled “**The Choice of the Comparator Group Prevents Interpreting the Primary Results**”), we argue that while a significant effect of groups on the number of successful days of diet could have concluded on absolute effect, null results cannot do the opposite. The control intervention indeed induced the same items' devaluation as the experimental group, and thus likely on the capacity to resist items' consumption. Without a zero-effect control comparator (baseline measures or a passive control group not modifying the stimulus valuation, or at least less than in the experimental group), we cannot isolate the absolute effect of the experimental training. This is clarified at the end of the mentioned sub-section of the Discussion p.19: “**Since we could not be sure that the control group experienced a meaningfully lower effect of training than the experimental group, and without pre-training measures of diet capacity, our contrast cannot distinguish if the intervention resulted in an absolute increase in participants' capacity to adhere to a diet.**”

3- The explanations offered in the "The devaluation effect was too large in the control group" section are not entirely clear. Furthermore, alternative explanations exist - as one reviewer pointed out, asking participants to avoid beverages in question may itself change people's evaluation of these beverages. These post hoc explanations need to be clarified, but again, they should not change the main conclusions of the research, which should be based on the confirmatory analyses.

This section has been clarified to address this question. We have now split the text of this section into two parts: i) the capacity of our group comparison to detect an absolute effect (p.19, sub-section titled “**The Choice of the Comparator Group Prevents Interpreting the Primary Results**”), and ii) the potential effect of the number of unhealthy-NoGo associations (p.20, sub-section titled “**The Role of the Number of Trained Items on the Effect of Response Training**”).

4- Some of the comments from the reviewers may require revising text that has already been approved at Stage 1 (e.g., the introduction and the methods sections). While I agree that addressing these issues will further increase the clarity of the text, there is also a strict policy on

permissible changes between Stage 1 and Stage 2 . As such, my advice is to discuss some of the raised issues in the general discussion, but not in the introduction or methods section, such as (1) whether the current measures truly circumvent shortcomings of self-reports, (2) the nature of the correlation between the length of training and the days of successful diet, (3) the reasoning for selecting sugary beverages as the target items etc. The introduction and the methods sections should be kept the same between Stage 1 and Stage 2.

Whenever possible, these comments have been the object of additional sections in the Discussion.

5- Perhaps contrary to my own advice above, some minor changes to the approved text seem necessary. Note that these changes all concern typographical errors, and are thus permissible changes between Stage 1 and Stage 2. More specifically, some sentences contain grammatical errors, such as:

1. Page 2: "The practice of these tasks have has been shown..."

2. Page 12: "Expectations on the study's hypothesis were also be rated..."

Furthermore, on Page 5: "that MIT interventions can facilitate restrictive diets". The acronym MIT is not defined in the text, nor used anywhere else.

We have corrected these mistakes throughout the manuscript.

Kind regards,

Zhang Chen

by *Zhang Chen*, 19 Aug 2024 12:27

Manuscript: https://osf.io/u9kqc?view_only=4934c0215f2943cfb42e019792a30b53

version: 1

Review by Matthias Aulbach, 01 Aug 2024 10:46

The Stage 2 manuscript “Sugary Drinks Devaluation with Response Training Helps Early Diet Adherence Failures” reports a randomized-controlled trial which showed inconclusive results of a combined cue-approach and Go/No-Go intervention on the length of abstinence from sugary drinks consumption. Further, item devaluation seemed unrelated to abstinence length. Abstinence length and amount of time spent on the training showed a small positive correlation. The manuscript is well written overall and makes relevant contributions to the field. My comments, appearing according to the order in the manuscript, are below.

We thank the reviewer for their positive evaluation. Following the decision of the recommender to comply with the guidelines of the RR that Stage 1 manuscript cannot be modified at Stage 2, we could not address the related comments. We however addressed as much of these points as possible in the Discussion section.

1- The timing of the task is spelled out right away for the Cue-Approach Task but not for the Go/No-Go Task. Is this asymmetry intended?

We agree that this point could be improved, but we cannot modify the introduction of the tasks as written during Stage 1 (cf. recommender's comment).

2- Page 3: “However, whether and how response training intervention impacts consumption behaviors remains largely unresolved.” The authors here introduce the question of “how” effects come about but the rest of the paragraph is not concerned with mechanisms but rather with the “whether” and measurement issues. Regarding the measurement issue, I think this manuscript present only a slight improvement, as it also uses self-report. I understand that soft drink consumption and yes/no questions are probably more reliable to measure than, say, amounts of different kinds of food but some issues of self-report are still not resolved (such as social desirability).

As the recommender suggested, a critic on the self-report measures was added in a “Further Study Limitations” sub-section of the Discussion. It now reads p.21: “We posited that self-reported adherence to a restrictive diet on sugary drinks would constitute a reliable index of real-world eating behaviour (cf. Introduction section). This measure, however, relies on the capacity and the will of the participants to report their behaviour accurately, which limits the ecological value of this data, like with any other self-reporting measure”.

3- Page 3: “letting the participant stop their training whenever they want in a two-weeks window enables to investigate the link of the intervention’s length on its real-world effect size.” – while this statement seems to avoid implications of causality, I think it still conveys that sense (the preposition “on” carries quite some weight here). It is important to be very clear that self-selected intervention length cannot be interpreted as a causal effect on behavior (as the authors clearly specify in the discussion).

We agree and concur with the reviewer that our interpretation in the discussion makes this point clear enough.

4- The paragraph on why the authors chose SBBs as a target could be a bit clearer, e.g., portion size is usually unambiguous because of typical packaging and consuming the whole packaging by oneself in one sitting (unlike most snack foods).

While the reviewer makes a relevant point, it would be difficult to include a clarification of our choice of sugary drink in the current Discussion section. We think the advantages of sugary drinks over other snack foods as stated by the reviewer are not obvious for VAS of explicit liking and self-report of restrictive dieting. The main reason for sugary drinks as target items was reproducibility as written during Stage 1 in the Stimuli sub-section.

5- Page 5: “Indeed, an additional 5 days of diet (extracted from a Cohen’s d of 0.5 with an estimated standard-deviation of 10 days) would be associated with physiological and cognitive modifications that might be detectable and considered relevant by the participants and the health care providers (i.e., reduction in appetite, higher energy level stability, induction of consumption habits, and realization by the participant that restriction can be maintained).” – could the authors provide a reference for this? As such, it is great that the authors make a substantial argument for a relevant effect size.

RR regulations do not allow to modify the sampling plan determined during Stage 1.

6- Page 5: “Unhealthy participants include self-report of past or current eating disorders, any visual or hearing disability preventing gamified training, and any olfactory or gustative impairment (including smokers consuming ≥ 10 cigarettes daily).” – do the authors mean “ineligible” here instead of “unhealthy”?

The reviewer is correct, it is a typographic mistake we have now corrected.

7- Page 6: “Before and after the training, participants rated in a random sequence their 8 most drunk items as well as the water items, from 0 (‘not at all’) to 100 (‘very much’) according to the question ‘Imagine drinking this, how much do you like it?’” – what exactly does “before and after the training” mean? After each training session? Or after the training phase?

We meant once directly before the first training session and once after the last training session. A timeline can now be found in the supplementary materials.

8- Figure 1: the 50ms delay described in the text is not depicted in the figure.

We cannot unfortunately modify this figure as validated during Stage 1. As this figure serves to summarize a GNG trial, it would be difficult to include all the timings while keeping it comprehensive and concise. An exhaustive list of all the parameters can be found in Table 3.

9- Page 9: “At the end of the training phase, participants received a weekly questionnaire asking if they succeeded in not drinking the trained sugary drinks and if not, the exact date of the first consumption.” – what exactly does “at the end of the training phase” mean? Maybe the authors could provide a figure with a timeline (at least in the supplemental materials).

While no changes are allowed during Stage 2, a timeline can now be found in the supplementary materials as suggested by the reviewer.

10- The analysis on stimulus liking/devaluation between groups is not presented in the results section but then reported in the discussion. Please also present this in the results section.

The exploratory analyses and results were moved from the supplementary materials to their own section of the main manuscript p.16-18.

11- Regarding this section, it could also be that the mere act of trying to avoid the drinks in question led to devaluation and that this effect is much larger than the training effect and thus hides any training effect.

We understand that the reviewer suggests that the dieting phase could have impacted the items' devaluation. Our instruction was to not start any diet before ending the training phase and filling the VAS of explicit liking. Because it took place before the dieting, it could not have influenced the devaluation. Concerning this section, we now have improved our interpretation of this exploratory result as suggested by both reviewers. It is now titled "**The Role of the Number of Trained Items on the Effect of Response Training**".

12- Page 17/18: again, the authors refer to analyses that were not presented in the results section. Please add this analysis as exploratory to the results section and then refer to it in the discussion.

As requested by the reviewer, the exploratory analyses and results were moved from the supplementary materials to their own section and are referred correctly in the Discussion section.

13- The interpretation of this analysis seems quite speculative, especially given the arbitrary, post-hoc threshold of 12 days. This should be very clear in the discussion and I don't think it's a good idea to include this in the title (after all, this is a registered report so the manuscript should strongly focus on pre-registered analyses)

We now have changed the title of the manuscript for "**The capacity of response training to help resist the consumption of sugary drinks**" and have toned down the weight of this exploratory analysis in the abstract, discussion, and conclusion. The section discussing this exploratory analysis is now titled p.19 "**Individual Differences in Baseline Dieting Capacities Influence Training Outcomes**" and use this result to highlight the null (e.g., p.21: "**Our result for a different effect between the control and experimental group only on early dieting failure rate suggests that the required diet could have been too easy to follow for healthy individuals not recruited for their consumption of sugary drinks, giving a potential explanation for the primary hypothesis' null result**"). The conclusion now reads p.21: "**The current registered report concludes that seven to twenty days of combined practice of a Go/NoGo and cue-approach 100% mapping training does not improve restrictive dieting maintenance in healthy participants when compared to a control group with 50% mapping, but exploratory results hint that it could still benefit at-risks population**".

14- Those issues set aside, thinking along the authors' line of reasoning, I would argue that response training mainly makes sense in the early phases of behavior change but then we could basically drop it?

While we agree that the effect sizes of food training might diminish with time, intervention duration could increase the persistence of the effects. Our study cannot identify which length of training is the most efficient as the measures were only administered once (baseline excluded) for the explicit liking and the dieting data only provided one point of measure per participant (i.e., how much they can abstain after the received training).

15- I am missing a limitations section. In my view, one important limitation is the focus on participants were willing to abstain completely – that's quite a different sample than those who might be willing to reduce consumption.

We agree, and we have added a limitation section in the Discussion, p.21 titled "**Further Study Limitations**".

Review by Pieter Van Dessel, 19 Jul 2024 13:54

The authors did an excellent job completing the preregistered study. The manuscript now reports valuable results from a well-designed study.

However, the main limitation of the current manuscript lies in the interpretation.

1- First, consider the title: "Sugary Drinks Devaluation with Response Training Helps Early Diet Adherence Failures." The procedure does not objectively involve "sugary drinks devaluation." Instead, it examines the effects of completing combined gamified GNG and CAT tasks. Furthermore, it is not accurate to state that completing these tasks "helps early diet adherence failures." This was not the research question examined. The main question was whether completing combined gamified GNG and CAT tasks increases the number of successful diet days. The answer is that it did not. A title that highlights this main result would be more appropriate. The current title focuses on an exploratory result, which is not ideal for several reasons (also see below).

While we agree with the reviewer on the mention of devaluation in the title, we kindly disagree on its description of the main question. Our main question was whether a 100% association training (experimental group) led to longer diet maintenance than a 50% association training (our control group). The equivalent items' devaluation in both groups suggests that the effect of training was identical in both groups. Without a zero-effect control comparator (baseline measures or a passive control group not modifying the stimulus valuation, or at least less than in the experimental group), we cannot isolate the absolute effect of the experimental training.

Because our main contrast was inconclusive on the main hypothesis, the new information provided by the manuscript was our exploratory finding for a difference between the two training regimens on early diet failure. This is the reason why we emphasized this result. That said, to follow the recommendation of the reviewer and of the recommender, and to better adhere to the philosophy of RR, we have now reduced the impact of the exploratory results in the rest of the manuscript, including the title. The title now reads: "The capacity of response training to help resist the consumption of sugary drinks".

2- The abstract also gives way too much attention to the exploratory result: "Finally, exploratory analyses indicated that the experimental group had improved diet adherence on participants failing the diet early (18% failure in the experimental group vs. 28.2% in the control group at first quartile). Our collective data seems to indicate that the effects of food response training may be particularly beneficial for individuals with difficulties adhering to diets. We suggest conducting a similar study to validate this exploratory result with a more fitting design." I would suggest removing this and providing a conclusion about the main study results.

Given the inconclusive nature of the main result on the effect of the 100% SR mapping response training on diet maintenance (the chosen 50% control group does not allow to conclude on this point because it had the same effect on self-reported explicit liking as the experimental training), we considered the exploratory findings as the most useful/informative study results. We however understand and agree with the point raised by the reviewer and the recommender and thus removed in the abstract the conclusion of the exploratory results on the overall study, and emphasized the null results of the primary hypothesis. It now reads: " We found that the 100% mapping of motor inhibition with the target unhealthy sugary drink cues in the experimental group

did not increase the number of successful days of diet compared to the 50% mapping in the control group (30.7 vs 29.8 days). We interpret this result as the effect on diet maintenance reaching ceiling in both groups, a hypothesis supported by the finding for equivalent target item devaluation in both groups. Food response training may also have not improved restrictive dieting adherence in resourceful healthy population, as supported by a difference in dieting adherence found only in participants with early failures (18% failure in the experimental group vs. 28.2% in the control group at first quartile). Given the lack of zero-effect comparator in our design, we could not conclude whether response training resulted in an absolute improvement in diet maintenance capacities" and "We suggest conducting a similar study including a zero-effect comparator group with no training or training on non-food items to test our primary hypothesis".

3- Also the discussion has limitations related to the interpretation of results. The title of one paragraph is "The devaluation effect was too large in the control group." It is unclear why the authors chose this title. Objectively, there was a reduction in evaluation in both groups, and this was not significantly different between groups. But this result doesn't imply that the devaluation effect was "too large." Of course control training can also have effects (many studies suggest this), but that is not a problem, in fact it is often a positive outcome.

What we meant with 'too large' was that the effect of the control group was too large for the control group to be considered as a 'no effect', zero-level, comparator measurement against which the experimental intervention could be used to assess its absolute effect. We have now clarified the title and the text of this sub-section to better explain this point. We now propose two sub-sections to discuss about i) the capacity of our group comparison to detect an absolute effect (p.19, sub-section titled "The Choice of the Comparator Group Prevents Interpreting the Primary Results"), and ii) the potential effect of the number of unhealthy-NoGo associations (p.20, sub-section titled "The Role of the Number of Trained Items on the Effect of Response Training").

4- The authors compare the results to their prior study and note: "The lower number of trained items resulted in a smaller Group x Session interaction." This may not be the case, as there could be other explanations, such as sampling differences.

Other potential variables have now been detailed. It now reads p.20: "The two studies only differed for the recruited population (healthy regular soda drinkers vs. healthy wanting to diet), the average number of days trained (13 in 2023 vs. 8 days in present study) and the number of unhealthy trained items (50 in 2023 vs. 8 in present study)".

5- They also state: "the number of NoGo associations in our present control group likely led the associative learning to reach its ceiling." It is unclear why this is "likely" the case.

This term has been modified to better encapsulate that our interpretation of this result is not absolute, and a more detailed explanation for this interpretation has been added. It now reads p.20: "If we posit that the effect of food response training evolves with the number of S-R occurrences (an assumption not yet resolved in the literature, but explored in [30,43]), the number of NoGo associations in our present control group may have led the effect of response training to reach its ceiling, in turn reducing the difference between the control and experimental groups".

6- Additionally, the meaning of “associative learning” here is ambiguous. Do the authors refer to a specific cognitive process underlying GNG effects, such as the formation of associations? Clarity is needed.

We are not aiming to refer to the mechanisms of actions underlying food response training. We thus have simply replaced this mention to "effect of response training" to keep it to the point.

7- Furthermore, they note: “the equivalent devaluation between the experimental and control groups in the present study suggests that the effect of unhealthy Go associations did not fully neutralize the effect of unhealthy-NoGo associations.” Again, this appears to refer to an associative cognitive process (if I understand well what is meant with “neutralization”). Note however that associative explanations of GNG effects are not well-supported anymore. If the authors want to refer to such explanation, it should at the very least be clarified that there are also other explanations, such as inferential explanations (related to demand compliant inferences, but also other types of inferences). The authors seem to allude to inferential explanation in the next sentence “Indeed the unhealthy-Go associations could have counteracted the unhealthy-NoGo associations if the participants were not expecting the intervention to be effective.” Here they refer to expectations (i.e., causal inferences). However, this point is unclear as the potential explanations are not well defined.

The terms used for the interpretation are now homogenized in this paragraph and made clearer. The explanation that expectation might have contributed to the effect of food response training is however referred to in the text as the reviewer understood. It now reads p.21: "Furthermore, for the large number of NoGo associations to create an effect in the control group equivalent to the experimental, this would mean that the Go associations on the target unhealthy items in the control group did not influence the overall effect of the intervention. This speaks in favor of the recent data that the understanding of the gesture performed in the tasks based on its instructions is crucial for an effect to arise [44,45]”.

8- The following sentences are also unclear: “Overall, we conclude that our control group did not allow an unequivocal interpretation of the mechanistic effect of an intervention with more than 150 unhealthy-NoGo associations per item. Since we could not be sure that the control group experienced a meaningfully lower effect of training than the experimental group, and without pre-training measures of diet capacity, we cannot conclude on the effect of response training on diet adherence (i.e., the primary hypothesis).” Are the authors suggesting that control training can also have an effect? This is true and has been evidenced by other studies. However, it is unclear why this is relevant. The authors initially posited that the contingency difference is the crucial working mechanism. If they are revising this idea, it should be discussed. This can be done with reference to inferential theories that indicate that learned propositions rather than contingencies that form associations are crucial (and, for instance, provide evidence in reference to instruction-based effects showing that contingencies are not crucial for effects to arise).

The reviewer is correct and understood our interpretation of the results. We do not wish to use this article as a discussion about the different cognitive processes involved in cognitive bias modification, but their involvement on our interpretation of the results is now explicit. It now reads p.20: “If we posit that the effect of food response training evolves with the number of S-R occurrences” and “This speaks in favor of the recent data that the understanding of the gesture performed in the tasks based on its instructions is crucial for an effect to arise [44,45]”.

This paragraph has been restructured to talk separately about i) the capacity of our group comparison to detect an absolute effect (p.19, sub-section titled “The Choice of the Comparator Group Prevents Interpreting the Primary Results”), and ii) the potential effect of the number of unhealthy-NoGo associations (p.20, sub-section titled “The Role of the Number of Trained Items on the Effect of Response Training”).

9- The paragraph on “The Role of Participant Baseline Capacity on Diet Adherence” explains one possible reason for the lack of effects for H1: the effect was only present for early maintenance (although it remains unclear why this effect would not be observed overall). However, this explanation does not warrant a separate paragraph. It should be discussed as one possible explanation and nothing more. Currently, this result is given too much attention (see also the abstract and conclusion) despite a p-value that is not robust ($p=.046$) and it being a pattern observed post-hoc and only at a specific moment in time (before 12 days), which resembles data dredging or p-hacking. The authors should be cautious here.

We have tempered down our conclusion to better reflect its exploratory nature, and the p-value has been removed to focus more on the effect size. This sub-section is now used to highlight the interpretation of the null results and is now titled p.19 “Individual Differences in Baseline Dieting Capacities Influence Training Outcomes”. It now concludes: “Our result for a different effect between the control and experimental group only on early dieting failure rate suggests that the required diet could have been too easy to follow for healthy individuals not recruited for their consumption of sugary drinks, giving a potential explanation for the primary hypothesis’ null result”.

Minor issues:

- Overall, it would be beneficial if the discussion were to explain the three hypotheses and possible explanations in more detail (e.g., motivation is mentioned for H3 but not elaborated).

As these negative results present non-ambiguous’ interpretations, we would like to keep it as it is to not overflow the Discussion.

- Adding Bayes Factors for the null results could provide important information (e.g., is there strong evidence for the absence of an effect?).

The Bayes Factors are reported both in the Results section and in the Discussion when discussing null effects, as registered. They are found with the abbreviation “BF₀₁”.

- It could be useful to report whether more days of training correlate with the number of successful diet days in the control group and if this correlation differs significantly from the experimental group.

This exploratory result has now been added to the supplementary materials: “No correlation between the days of training and the number of successful days of diet was found in the control group (r [95% CI] = 0.075 [-0.1; 1], $t_{[88]} = 0.71$, $p = 0.24$, $BF_{01} = 3.25$). This is not significantly different from the correlation observed in the experimental group when comparing their confidence intervals (r [95%CI] = .22 [0.05; 1])”. The plot of this correlation can be found at Supplementary Figure 3.

- Several studies in CBM research have found that CBM does not affect real-life behavior in general groups (in contrast to clinical groups; see papers by Reinout Wiers). Discussing this could be beneficial.

We appreciate this reference that has now been added to the manuscript p.19: “as also supported by cognitive bias modification research finding no effect of real-world measures on healthy samples as opposed to clinical studies [46]”

- There is not much information about study limitations related to the specific sample, self-report measurement,...

A limitation sub-section has now been added p.21 titled “Further Study Limitations”.