Author’s response to reviews

Title: Swiss chocolate and free beverages to increase the motivation for scientific work amongst residents – A prospective interventional study in a non-academic teaching hospital in Switzerland

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Author’s response to reviews:

Dear Editors,

thank you for considering our original manuscript (TRLS-D-18-00897) entitled:
“Swiss chocolate and free beverages to increase the motivation for scientific work amongst residents – A prospective interventional study in a non-academic teaching hospital in Switzerland“

for consideration of publication in Trials and for giving us the opportunity to resubmit a revised manuscript.

We like to thank you and the two reviewers for the comprehensive and helpful comments. We responded to all comments in our attached point-by-point response and revised the manuscript
accordingly. All changes to the manuscript were highlighted in red/blue using the track change version. Additionally, we provide a revised manuscript as clear file without track changes.

I would be pleased if the revised manuscripts meets your criteria for publication in your journal.

Sincerely and on behalf of all the co-authors,

A. Rühle

Point-by-point Response

Reviewer #1:

Reviewer #1: * Major comments

- Overall: thanks for submitting this manuscript; I commend your decision to put time into writing up and submitting 'smaller' pieces of work like this, i.e. those without funding. Publication of evidence like this enriches the literature. However, as detailed below, I feel there are currently significant issues with the methods (which could be fine if limitations are fully acknowledged), clarity of reporting and the validity of some claims made. I also think this needs to be made more broadly relevant outside of your local context, and better linked to existing research around recruitment in trials.

- Although I think there are not significant ethical concerns raised by this study, the general concept of incentivising clinicians to enrol patients into trials raises questions of conflicts of interest, and clinicians taking risks to obtain the rewards, not necessarily acting in patients' best interests. I think the paper should at least touch on this, if only to confirm that giving chocolate and drinks is probably not too concerning in this regard.

- More clarity is needed about the use of the vending machines in the randomisation process - see comments below. Could this work in multicentre studies and/or studies with complex randomisation methods?

- The study design and statistical methods are not adequate to make the claims currently made.

- The reporting of the results is difficult to follow. For example, some results are presented as comparisons between the two trials involved, some as comparisons between the timepoints of the two surveys (even though it is hard to interpret what this comparison means, because the soft drinks machine was already in use prior to the first survey timepoint). It would be useful to be consistent about how the results are reported. Other comments on this are below.

The authors thank the reviewer for the very helpful and enriching comments, we revised our manuscript thoroughly and adapted it addressing these relevant concerns, hopefully achieving to make the manuscript easier to read and better linked to the existing research. Also we admit
enthusiasm concerning this smaller piece of work might have caused making claims instead of assumptions and we have worked on displaying the result more clearly.

* Minor comments

- Title: check with the journal, but I am not sure the sort of title in this manuscript is allowed in Trials, i.e. one that makes a claim ('...free beverages increase the motivation...'). In any case, as mentioned elsewhere, I think your grounds for making that claim are not strong.

- Title: the wording of the title is not that clear, for example the meaning of the word 'instruction' and the lack of reference to any sort of study design.

Thank you, that is truely a relevant critique, we changed the title the accordingly.

- Abstract: I have not fully reviewed this as I feel substantial change is required to the main body of the paper; I would like to review a revised version at the next round of reviews, please. You are right, we also changed the abstract after revision of the manuscript and we would be pleased to have you review it again.

- Background, line 2/3: '...effectively recruit as many eligible participants as possible...' - surely you want to reach a pre-defined sample size in efficient time, rather than recruiting as many as possible. That is correct, we changed the sentence accordingly.

- Background, line 4: can you back up your claim that recruitment processes 'can be influenced in various ways'? Or perhaps reword to make clearer what you mean? We described, referring to existing literature, what we thought about writing this sentence.

- Background, paragraph 2, line 1: 'participant recruitment is often conducted during first patient contact...' - suggest you supply a reference for this, or make clear that this is in your experience. This truly is our experience, we clarified that in the manuscript.

- Background, para 2, line 2: you say recruitment is 'performed by a young resident'. Is it? How well does this fit with the principles of good clinical practice, where we'd expect all clinical staff to be fully trained and qualified? And can you guarantee a fair and adequate informed consent process if clinician is inexperienced? Is there any additional oversight of the informed consent process if 'young residents' are doing this? You don't have to amend the text to answer all these questions, but be aware that the reader may be surprised by this sentence. Thank you for your concern, of course a fair and adequate informed consent process has to be assured during a trial. We rephrased the paragraph to make it clear that in our hospital although the resident is in charge of informing a patient of a potential participation and furthermore take care of the inclusion, this is overseen by a senior doctor and/or trial coordnînator/investors that take care of the resident beeing up to date on the matter or not assist in informing the patient. What we wanted to express is, that in order to assess a patient for a potential participation, that
residents needs to know about a trial and is willing to potentially do extra work associated with the consideration of a patient for a trial.

- Background, para 2, line 3: 'challenged by the imponderables…' - minor comment, but I'm not sure the tone of this is right here - I think it would be good to keep it factual if possible. Tone of the sentence was changed to stay factual.

- Background, para 2, line 3: 'Typically, this resident personally does not benefit, nor has any insight into the entire background of the trial.' Two problems with this: 1) I think clinicians do benefit, in various ways, such as in their career, personal interest in research, and sometimes in meeting recruitment targets the site has signed up to. 2) The comment about not having 'any insight' seems worrying, similar to the point above about inexperienced staff recruiting patients. How can informed consent be adequate if the clinician has 'no insight' into the background of the trial?
It is also our opinion, that a clinician benefits in various ways from scientific work, but it is our experience that this is not everyones opinion. There are colleagues with strictly clinical interests that do not see the need to do research and there are hospitals in which the career does not rely on research. Regarding comment 2, we addressed this matter and of course informed consent process is assured to be adequate by the responsible senior. To assure a patient understands the current state of science and the potential benefits of participation in a trial for the patient and future patients, it is indispensable that the resident is informed adequately.

- Background, para 2, line 5: 'Furthermore…' - this sentence about clinicians having diverse interests - can you back this claim up with evidence?
Actually we did not search for literature concerning this topic but in exchange with different colleagues over the years it is obvious that not all colleagues find pleasure in scientific work as well as some colleagues leave clinical work for purpose of intense research time. This is what we meant with this paragraph to explain why the focus of our trial is the motivation of residents who might not be intrinsically interested in research.

- Background, para 2 final sentence: '...and thereby success…' - check this wording as it isn't right at present. I think the intention is for the verb 'influencing' to apply to 'the recruitment rate' and 'success' but this does not read very easily.
Thank you, we rewrote the sentence.

- Background, para 3, first sentence: I do not believe you that there is no literature addressing motivation in trial recruitment. How much time have you spent looking? A relatively quick way to find evidence about recruitment is through the ORRCA database, if this helps. As per my major comment, above, I think this work in general would benefit from more clearly linking to and building on existing evidence in this area (which is substantial, though not necessarily strong)
We thank you for this contribution, as you mentioned there is literature addressing the difficulties of the recruitment period and suggestions to improve this period. Only few studies focus on the recruiters rather than the participants. There is literature concerning alterations of the information process or reminders, there is also literature dealing with gratifications but to our
knowledge no study on a simple system like ours with direct observation of the results during randomised trials carried out at the same time. Addressing this, we rephrased this paragraph.

o Background, para 3, line 2-3: does reference 6 definitely show that 'motivation is not sufficiently triggered by providing information alone'? The parts of that work about information are about information for trial participants, though there are some sections about recruiter training. Yes, we believe so after re-reading the paper.

o Background, p5 first line: perhaps more accurate to say you decided to try to increase motivation, rather than just deciding to do it? (Because it's not really in your control) We changed the sentence to make clear that this was our intention.

o Background, p5 same sentence: '...increase motivation to participate...' - I think you should make the whole sentence clearer that you mean motivation amongst recruiters, rather than participants. 'Motivation to participate' could certainly be read as referring to trial 'subjects'. Thank you for the revision, it is crucial that it is clear that the interventions we used addressed the recruiter and not the patient. We changed the sentence according to your suggestions.

o Background, p5 line 2/3: 'Out hypothesis is...' - should it be 'was'? Thank you, we rewrote the sentence.

o Background, p5 line 6: I don't think you can claim this study is 'unique'. Thank you, we rewrote the sentence.

o Background, p5 line 7/8: 'reward based positive randomisation tool' - this is not a clear description, though I appreciate there is more detail in the methods. I think 'randomisation tool' is not a helpful term (as discussed elsewhere) if it is just the method of delivering the result of randomisation (as opposed to actually doing the randomisation). I'm also not sure what the word 'positive' means here. For easier reading we changed this to randomisation tool initially, but of course this is technically not true. We made sure to change it in the manuscript. Positive in this case means positive intensification as in pavlov's conditioning. We changed that.

o Materials and methods, line 4: 'we identified two positive influencing factors' - how did you identify these? Might it be more accurate to say that they were proposed as possible factors? That is Wright. We changed that.

o Materials and methods, line 4: 'we identified two positive influencing factors as means to influence...' - check the wording regarding repetition of the word 'influence' Thank you, we rewrote the sentence.

o Materials and methods, line 5/6: 'adequate information...was provided' - how do you know it was adequate? Maybe you just mean lots of information, or frequent information? And is it useful to add how the information was provided?
We reviewed this part and hope to have achieved a more precise choice of words to explain what we meant with adequate information.

- **Materials and methods, line 8**: ‘...at a regular interval during recruitment...’ - what interval, specifically? And suggest you clarify 'during recruitment' - I suspect this means during the recruitment period for the trial rather than during each patient's recruitment process. The interval was added, we initially omitted it, since we thought this to be irrelevant.

- **Materials and methods, line 9**: 'soft drink beverages' - this is tautological as 'drinks' and 'beverages' mean the same thing. Suggest just 'soft drinks' will do. That is correct, thank you.

- **Materials and methods, line 9**: 'at the time of randomisation' - before or after? From later descriptions, I believe this was just after randomisation (as 'delivery' of the randomisation result). We changed that in our manuscript that the soft drinks were received during randomisation since the randomization result was sticking to the cans.

- **M&M, section 3.1, line 1**: I don't think the words 'Ethical Committee' need capital letters at the start.

- **M&M, section 3.1, line 2**: suggest 'in the German Clinical Trials Register', not 'at' Changes were made, thank you.

- **M&M, section 3.1, line 4**: recruitment took place in the emergency department; could you please clarify if these trials were in an emergency care setting? I presume not (based on later information), but emergency care might mean patients did not give informed consent due to temporary loss of capacity. This would make the potential conflict of interest involved in incentivising clinicians to enrol (mentioned in Major comments, above) more of an issue. Thank you for the concern, we changed the manuscript, since this is something that needed to be cleared up. Although the procedures were emergency operations, all the patients were conscious and had enough time and information to give informed consent. If this was not the case, patients were not included.

- **M&M, section 3.1, line 5**: 'follow up controls' - not sure what this means - perhaps follow-up assessments? Precisely, that is what we meant.

- **M&M, section 3.1, line 6**: should be 'patients were informed' (not 'where')
- **M&M, section 3.1, line 6**: should be 'consented to', not 'in' We change these mistakes.

- **M&M, section 3.1, line 6**: 'consented [to] further use of their data as for example a following survey' - I can't quite follow the meaning of this. If it isn't relevant to the rest of this paper, you could probably remove it. If it is relevant, please clarify the meaning. What we meant with this sentence is, that when patients decided to participate in a trial they also consented, that the data could be analyzed for a different cause. An example for this is this study,
although there is no patient data of the two trials display in this study, we wanted to state that the patients gave consent of use of their data.

o M&M, section 3.1 Trial One, line 2/3: minor comment, but this reads as if the patient has no choice in the matter - they are apparently informed and then the resident completes the consent form. At what point do they get a choice about whether to participate?
We cleared this rephrasing the paragraph. Patients were informed about the potential trial after consenting to the operation. If they were willing to hear about the trial they were informed about the trial and had the opportunity to participate.

o M&M, section 3.1 Trial One, line 3: probably should be 'complete the informed consent form'
Thank you, we rewrote the sentence.

o M&M, section 3.1 Trial One, line 5: here and elsewhere I think you should give more details about the randomisation method. You say the soft drinks machine is related to the randomisation process. What is the randomisation method, and does the drinks machine actually perform the randomisation, or just deliver the randomisation message, with randomisation performed by a computer program? If the machine does indeed do the randomisation, is that because you are only using simple randomisation in these trials? If so, is that methodologically justified in the trials' designs? And would use of the machine be useable in more complex randomisation processes?
You are right, this was not quite understandable, we changed this to clarify our randomization and also addressed the concerns in the limitations section. We used 1:1 randomization, therefore we first used blinded enveloped. These were prepared by the investigators and equipped with the necessary sheets as well as the randomization result; later when the soft drink machine was used the envelopes included two coins to use for the soft drink machine. In the machine the cans also were prepared by the authors and had a sticker on them that delivered the randomisation result.

o M&M, section 3.1 Trial One, line 7: estimated additional work of 15 minutes - how did you calculate this? Can we be assured that it's a reliable estimate?
This was not calculated but measured by the authors during recruitment of patients that were carried out by the investigators of the trials. We believe this amount to be reliable but specified this in the manuscript.

o M&M: for both these trials, please also state the sample size, the number of centres involved and if any centre-specific recruitment targets. If both studies are single-centre, I think you could frame the whole paper in this context and consider in the discussion whether your approaches could be scaled up into multicentre studies.
We addressed this by change of the manuscript, both trials were single-center studies. The use of our approach in a multicenter study is discussed in the limitations section, we think it could possibly be used, but a more complex randomization could be difficult. Also equipping the vending machine is quite time-consuming what may limit the use.
o M&M for both the trials: were these trials having recruitment problems that needed resolving? Or were there similar trials previously that had struggled to recruit. This would be helpful context / would help understand your motivation.

We tried to make this more clear, these two trials had no recruitment problems, maybe since we used the approach from the beginning. Our motivation to investigate the possible influences of the motivational approach was the observation that trials that already were running in our hospital had low inclusion rates and residents oftenly did not know about the trials at all. Also many residents were annoyed of scientific work, since they found it to only increase their work load. When the two new trials were established we wanted to make sure, that they run smoothly, so we came up with the idea to motivate and inform our colleagues.

o M&M Trial Two - the comments on the Trial One section also apply. Regarding the time estimate - given for this trial as 5 minutes additional work - this seems extremely small, and apparently includes the informed consent process. Is the patient given less than 5 minutes to agree to the study? Is this ethical?

As explained above the cleared this up in the manuscript. The time additional time does not represent the time the patient had to consider participation but only the amount of time the resident usually had to spend additionally due to the trial. Since patients upon interest of a trial received a detailed information form the resident did no need to explain the trial in full-length but only discuss possible questions and then complete the necessary forms. In trial 2 these forms were much shorter, corresponding with less time the resident had to spare.

o M&M, 3.2 line 1/2: 'A well-informed and motivated resident is...more likely to remember the existence of the trial’. I think I know what you mean, but this reads a little unclearly to me. Perhaps you mean they are more likely to remember to approach patients as part of their routine clinical work. Or is it a matter of remembering to prioritise one trial over another?

Thank you, we meant that a resident being aware of trials and willing to do the extra work will remember to approach eligible patients as part of the routine clinical work.

o M&M, page 8, line 2: 'being up to date in a specific area enables [the clinician] to inform the patient accurately, which increases the probability to convince the patient of the importance of an ongoing trial…' - does it? I think this is debateable. Unless you can provide convincing references for this claim, I would remove or adjust it.

We backed this up with a reference.

o M&M, 3.3, line 2: should be 'would increase mood'

o M&M, 3.3, line 4: not sure about 'according', suggest 'using'

Thank you, we changed the words.

o M&M 3.3, Swiss chocolate, line 2: these claims about the benefits of chocolate are resting on one reference - is that perhaps a bit selective? I imagine there is a significant body of work on the effects of sugar on productivity. Did you find anything more comprehensive, for example a systematic review on this?

You are right, we backed it up with a review.
o M&M 3.3, Swiss chocolate, line 2: 'we chose the best chocolate, Swiss chocolate…' - Belgians may disagree! And I suggest you remove this as it is not the right tone (i.e. not objective). Did you ask your population what chocolate they might like, or just assume they would prefer your choice?
Thank you, you are absolutely right this was a bit stuck-up and is to be explained by the high national proudness of people in Switzerland towards their chocolate. But of course this is something that should not be found in research so we removed it. The population was not interviewed regarding their favourite chocolate, we just bought a range of different styles.

o M&M 3.3, Swiss chocolate: similar to the last point above, was anyone unwilling or unable to eat chocolate, because of personal preference or allergies or anything else? No information on this is presented.
Luckily there were no nut allergies in our population.

o M&M p9, first line: 'Free soft drinks were identified…' - did you carry out any work beforehand to find out if staff wanted this?
In our hospital the residents frequently spend their time-off together, therefore we observed the frequent drink choice, but of course in a cohort not as familiar as ours there might be problems.

o M&M p9, line 1-3: check the sentence structure - the second part ('we decided…') needs a better link to the first part, e.g. with 'therefore' or similar.
Thank you, we rewrote the sentence.

o M&M p9, line 3-5: as mentioned above, you should make clear whether the vending machine was just delivering the results of the randomisation performed elsewhere, or whether it was actually performing the randomisation (in which case, there are various additional details we need about this - see above).
We addressed this topic in a preceding paragraph according to your concerns.

o M&M p9, line 5: I'm not sure 'purported' is the right word - it has the connotation of making a false claim. Suggest 'proposed'
o M&M p9, paragraph 2, line 6: 'pursing' - this probably isn't the right word, perhaps it should be 'pursuing'?
Thank you, we rewrote the sentences.

o M&M p9, paragraph 2, line 9: 'given the overwhelmingly positive response…' - this seems like a result, should it be in the results section?
The aim was to explain why we changed the randomization in trial 1, therefore we decided to explain this in the M&M part.

o M&M Survey, p10: what software was used to carry out the survey?
It was an online freeware survey, we used surveymonkey.com. We changed the manuscript to mention this.

o M&M Survey, p10: Figure 3 is referenced, but is not readable in the format I have it. Is it an image? Would it be better as a text-based format, e.g. Word?
We changed this.

- M&M Survey, p10, line 4: suggest a new sentence is started at the end of 'target population'.
  Thank you, we rewrote the sentence.

- M&M Survey, p10, line 5: would you consider adding the cover letter as supplementary information so that readers can see how the survey was framed?
  Of course, as mentioned in the manuscript additional information is given upon request.

- M&M Survey, p10, line 5: check the wording of '...as well by a cover letter as in person'.
  Also, what did this in-person information consist of? Is there any risk that the in-person information biased the survey results?
  What we meant was, that the residents were informed during the morning meeting that there will be a survey-link send out and that we would appreciate if residents would consider taking the survey. We don’t think that this biases the results of the survey.

- M&M Survey, p10, line 7: I think the survey was sent out at a point in time, not a period (though you were asking about a period -but that seems slightly different). This applies to the mention of the 'second period', further down the same paragraph.
  Thank you, we rewrote the sentence.

- M&M Calculations, line 1: why were periods of 6 months chosen? This seems somewhat arbitrary, and for Trial 2 recruitment hadn't started for the first few months of period 1.
  Since the estimated inclusion period was to last 12 months and in a preliminary analysis we found 50% of the inclusion being performed after 6 months, we chose to changed the randomization delivery as mentioned above owing to the fact of positive feedback of our colleagues that asked the soft drink machine to be used in the trial 1 as well. Since we initially bought the vending machine for trial 2, this worked with the machine from the beginning.

- M&M Calculations: recruitment rate needs to be more precise than just number of referred patients / number recruited. We would need to look at the reasons people did not take part - it could be that lots of people were ineligible for the trial, for example. I think your proposed intervention is supposed to increase clinician engagement and therefore increase the proportion of patients who are willing to join trials. Is there specific evidence that this happened in response to the clinician rewards?
  We changed that to make it more clear that the inclusion rate represents the percentage of included patients of the cohort of eligible patients and not the referred patients.

- M&M Statistics, line 3: you say you calculated mean or median, but what outcome measures are these referring to?
  Part of the survey question were scaled from 0 to 10, for these questions the median an interquartile range was calculated.

- M&M Statistics: the text should make clear which parts of this were prospectively designed, or otherwise which were designed post hoc or as you went along.
Thank you for that comment, we changed the manuscript to make it clear what parts were prospectively designed (the two trials) and what was designed as we went along (the survey).

M&M Statistics: you have said a two-sided p-value of $<0.05$ was considered as a threshold of statistical significance, but it isn't clear which primary question you would apply this to. If you are applying this to many tests then it becomes meaningless.

Thank you for that comment.

M&M Statistics: you say you have no missing data (which is probably a result not a method), but then at the start of Results you say not all invited participants took part in the survey - this is missing data. What if the views of the non-respondents - which you did not capture - are significantly different to those of respondents?

You are absolutely right, we changed the manuscript accordingly and also commented this in the limitations section.

Results, line 1: why is there a different denominator in round 1 and 2 of the survey? Were they different people? If so, how can we make any comparisons between the rounds of the survey?

There were more people in the second cohort, since new residents were in the target group additionally to the ones from the first round. Sadly the survey answers were anonymously so we are not able to pair the results of the first and the second survey.

Results, line 2 and generally: a p-value is given but it isn't clear what this is supposed to mean.

In general, suggest you are more sparing with p-values as the experiment does not seem set up to produce robust tests of statistical significance. Any values given are likely to be explorative only.

You are right, nevertheless we believe although only of explorative value, the p-value helps understanding the data.

Results, line 4: numbers are given for interest in clinical scientific work, but it isn't explained what the scale is.

The scale was initially explained in the survey, which you were not able to see clearly as you commented. We therefore changed the figure and made sure to include a more detailed explanation of the survey questions in the main text.

Results, line 5: 'All participants indicated...' how did they indicate this? Is there a survey result to give here? Was the question that found this result a leading question (e.g. 'do you agree that...')?

Same as above, we described this better in the main text and rephrased that paragraph.

Results, paragraph 2, line 2: what is the value of asking a preference between the trials? Similar interventions were implemented in both trials, so it's hard to draw a meaningful conclusion from the difference. The results seem to show that more people had a preference either way at the time of the second survey, but it's hard to know what this means.

Thank you for making clear that this needs more explaining, we changed our main text according to that. What we found regarding the data of this question was that, of course residents had a preference during first an second survey and we were expecting that trial 2 would be preferred, since it caused less work than trial 1 and it had the soft drink machine with the free beverages for
each randomisation from the beginning. Therefore this was the trial with only a little extra work and free drinks. What we wanted to find out was, if it was possible to increase the preference for trial 1, although it was more work, with the soft drinks. What we found was that still more residents preferred trial 2 but the percentage of residents preferring trial 1, increased in a even higher percentage.

o Results, paragraph 2, from 'The most common reasons…': I suggest reworking all of this, as for me it is difficult to interpret what it all means; is the comparison between the two survey timepoints very meaningful? Were these aspects ones you asked about specifically (and if so, why these?) or ones people raised spontaneously in response to open-ended questions? As above, there is a problem with varying denominators (18, 22, 32). There were no open-ended question in our survey, since we found comparing those not reasonable. We rewrote the paragraph to make it clear what we wanted to achieve with the questions and also why we found it reasonable to compare the two time points on the one hand and the two trials on the other hand.

o Results, paragraph 3, line 1: what does 'maximally motivated' mean? How did you measure whether people were maximally motivated? Or is this just subjective reports from individuals? If so, is this reliable? How does this contrast with 'gradable motivation' in the same paragraph? And how have you defined and measured that? Maximally motivated is a subjective report from the residents. The question is showed in the survey picture, residents were asked if they felt their motivation could be ameliorated and if so by what or if they already felt that their motivation for scientific work was already maximal high or if they just felt no motivation at all.

o Results, paragraph 3, line 4: suggest you don't need the word ,respectfully'
We changed the whole paragraph.

o Results, paragraph 3, line 3-5: is it useful to know this comparison between timepoints in terms of staff asking for more information? What can we learn from this?
As mentioned above, we described more detailed what we think we can learn from this survey.

o Results, p13, line 1: '...motivation would be increased if … work load was smaller'. Isn't this completely obvious? More gain for less time commitment? Why might we expect people's motivation to not increase if they had to commit less?
Of course it is obvious, that less work is more likely to be a motivating factor and our data showed this as well.

o Results, p13, line 2: you say the workload remained stable, but how did you measure this? And are your measurements reliable?
We rephrased that to make it clear - the workload that remained stable was the additional work the resident had to do if a new patient was included in one of the trials. Since the recruitment process itself was not changed by the cola machine, this workload remained stable. The