Correction to: Early-stage studies to larger-scale trials: investigators’ perspectives on scaling-up childhood obesity interventions

L. von Klinggraeff1*, R. Dugger1, A. D. Okely2, D. Lubans3, R. Jago4, S. Burkart, R. G. Weaver, B. Armstrong, C. D. Pfedderer1 and M. W. Beets1

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Following publication of the original article [1], the authors identified an error in Table 1. The correct table is given below.

The original article [1] has been updated.

Author details
1 Arnold School of Public Health, University of South Carolina, 921 Assembly Street, Room 130, Columbia, SC 29205, USA. 2 School of Health and Society, University of Wollongong, Wollongong, Australia. 3 Priority Research Centre for Physical Activity and Nutrition, University of Newcastle, Callaghan, Australia. 4 Centre for Exercise, Nutrition & Health Sciences, School for Policy Studies, University of Bristol, Bristol, UK.

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*Correspondence: vonklinl@email.sc.edu
1 Arnold School of Public Health, University of South Carolina, 921 Assembly Street, Room 130, Columbia, SC 29205, USA

Full list of author information is available at the end of the article
| Theme | Definition | Exemplary Quote |
|-------|------------|-----------------|
| I. Conceptualization of Intervention | | |
| Gathering Information | Conduct an initial exploration of potential interventions including literature reviews and qualitative inquiry | 1a “I like to make sure that I’m informed by investors in the program. So if it’s a school-based program, I’d be speaking to the school, the children, the parents, or people who are experts in that area, to make sure that the program is what they are looking for, what they need.” ID6 |
| | | 1b “Looking at the evidence based behavioral strategies techniques that have been shown to be useful within that specific population, you know, highlighting the sort of the mechanisms of actions.” ID23 |
| Measurement Logistics | Will study measures result in a sufficient amount of quality data. | 2a “Do we want to do DEXA scans in this particular trial? Will people accept these DEXA? Let’s try it. Let’s see. Will they wear FitBits? Will they wear them 24 hours? Will they wear them at night so we can monitor what’s going on at sleep? You’re getting pilot usability and feasibility feedback.” ID19 |
| | | 2b “You use pilot studies to check your measurements, to be sure you can do them. The measures I do are more complicated to deliver because we’re not located near the participants.” ID5 |
| Trial Parameters | Will intervention and study design be well-received by the target population and whether study can be executed with sufficient fidelity to produce a valid test of intervention efficacy, feasibility, and acceptability | 3a “Can you recruit at the rate that you think? Will people deliver the intervention? Can we assign people to control? And is that acceptable? Testing all of those different parameters.” ID19 |
| | | 3b “You’re tracking a whole range of methodological considerations, testing the actual program or intervention, and it gives you an opportunity to see the acceptability, the feasibility, of delivery, the quality.” ID17 |
| Mirror Larger Trial | Intentional consideration of the alignment between preliminary studies and future, larger trials of the same/similar intervention | 4a “The pilot study has to be conducted exactly the way the future large-scale study would be conducted. Naturally, it has to be conducted on a smaller scale because of the funds available at that time.” ID22 |
| | | 4b “In terms of mimicking what would actually happen in a definitive trial sometimes you can’t know what will happen until you’ve made these mistakes.” ID10 |
| II. Interpretation of Pilot Study Results | | |
| Process Implementation Measures | Measures of process implementation including fidelity and dose, as well as indicators of participant engagement such as recruitment, retention, and qualitative feedback | 5a “We knew we could recruit and retain. We knew the kids liked it, the staff were reporting the engagement was high. That was key because the intervention required quite high engagement levels. We could get good physical activity data with high compliance. That was a big tip.” ID13 |
| | | 5b “I want to see some data that says, number one, people come and number two, people will stay in till the end.” ID9 |
### Table 1 (continued)

| Theme                          | Definition                                                                 | Exemplary Quote                                                                                                                                 |
|-------------------------------|---------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Indicators of preliminary efficacy | Markers used to assess potential efficacy such as trends in primary outcomes, effects of theorized mediators, and tests of statistical significance. | 6a “Pilot studies can provide some evidence to move forward, but they are often underpowered to detect differences. So, I think pilot trials have a place, but I don’t think it should be the deciding factor.” ID2  
6b “What we did have was some pre and post data, and a hunch that we liked it” ID4  
6c “A pilot study has to provide some evidence of efficacy. The suggestion to conduct a feasibility or pilot study and not worry about the outcome … we could waste a lot of resources if we had that view.” ID14  
6d “It’s a bit of a conundrum. I do think that you can falsely say ‘oh, well we didn’t show an effect in our preliminary efficacy because the sample size was small, and the timing was off.” ID24 |
| Inflated effects               | Aspects of pilot studies that may inflate indicators of efficacy.          | 7a “The participants in a pilot study are the cream of the crop, and when you’re doing the larger study those people have already participated.” ID5  
7b “In the pilot study we had teachers delivering intervention and in the main trial we went to the core non-degree staff delivering the intervention. So that probably inflated the effect of the pilot.” ID21  
7c “There’s no point doing it, showing all this promise from a pilot study when many of the components have no chance of going to the next stage.” ID17 |
| Concept II: Scaling Piloted Interventions |                                                                 | 8a “We had some effects, but we thought we could make them better. So we added more teaching practice and we revised the activities to make sure that they maximized physical activity opportunity.” ID3  
8b “The participants just weren’t engaging beyond our initial clinic visit and that suggested to me, that what we had developed was probably not going to be sufficiently engaging.” ID15  
8c “If the core aim of what you are aiming to achieve has to change substantially, then I think you should reconsider whether it warrants another pilot.” ID15 |
| Re-piloting Interventions     | Engaging in more than one round of preliminary testing to enhance intervention effects or address identified obstacles | 9a “We had very good partnerships. We were embedded in the local school boards and they saw it as very useful from both a health and an educational point of view and the larger scale trial was really just a larger scale longer version of the pilot study.” ID20  
9b “We were mindful that the teachers in the intervention schools may not be as motivated as those in the pilot schools. So we had to give them some flexibility around how they would be implementing the intervention.” ID18  
9c “As we moved from a pilot study to a larger-scale trial, it was not possible to get one person to train all the teachers, so we kind of had to move to a train the trainer model.” ID10 |
**Table 1** (continued)

| Theme            | Definition                                                                 | Exemplary Quote                                                                                                                                 |
|------------------|---------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| **Funding**      | Choices made to conduct, and publish, preliminary work were based upon investigators perceptions of the difficulty, and value of the preliminary work as it related to obtaining additional funding. | 10a  “The primary outcome for our larger study might be the secondary outcome for the pilot study. In our pilot study, we might look at a behavioral outcome rather than a clinical outcome because we know that we know we are not going to show anything on the clinical outcomes” ID15  
10b  “The big incentive of having good pilot data is getting funding.” ID7  
10c  “I don’t do a pilot study unless I know it’s worthwhile” ID6  
10d  “Journals don’t want to publish no results, and pilots are often null” ID2  
10e  “If you focus on publications quality, then pilot study publications might not be the highest quality publications. They might not be getting the best or highest ranked journals” ID3 |
| **Adaptions**    | Identification of obstacles with study design or intervention protocol and brainstorms ways to ameliorate the identified problems | 11a  “We received feedback from the first feasibility trial and they said this certain activity is really good. So we focused on the ones that worked really well and then the feedback that we got from the second study was that these didn’t work so well” ID3  
11b  “The other key difference is that based on our pilot study intervention was having more of an effect on children with a propensity for overweight or obesity. So in the larger scale study, we focused specifically on those children” ID7  
11c  “If people didn’t adhere to what you’re doing, if you couldn’t recruit enough people, if satisfaction was a complete fail .... I would have probably done adjustments along the way to make the pilot successful, but if I hadn’t, then okay, I’d need to pilot this again” ID24  
11d  “I’d consider whether you have differential dropout or follow-up between the intervention and control groups. And if you do, then you will need to see how best to address that before moving on to the full trial” ID13 |
| **Challenges**   | Challenges encountered when scaling pilot studies                          | 12a  “In the pilot we had a small amount of group of teachers who were very motivated and who want to bring about a change but in our larger trial we had multiple teachers, multiple schools. So staff felt like their principal or their head of department had a sort of top-down approach” ID18  
12b  “The control group was more powerful than we expected and the intervention didn’t look that meaningful next to the control group. That made it challenging argue for the larger study” ID6  
12c  “For the larger study, going into low income schools in more disadvantaged areas, recruiting, retaining, and gauging is just so much harder” ID14 |
### Concept IV: Reflection

| Theme                  | Definition                                                                 | Exemplary Quote                                                                                                                                 |
|------------------------|-----------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| Lessons learned        | The process of executing a pilot study, and subsequently larger trial, provided investigators with valuable insight | 13a “We’ll sit there in a room for a day, go through things, and ask ‘What do you think?’ and then say ‘oh well that didn’t work, this didn’t work.’ So we put our minds together and, use those lessons from our other trials, to move forward.” ID6  
13b “I think you’ve got to have the methodological questions built in and you might also want to do a much more detailed evaluation of behavior changes rather than just focusing on the outcome which you know in a larger trial you might not be able to collect.” ID4  
13c “My lesson was to not sit there too long and try to do multiple feasibility studies.” ID11  
13d “I learned a lot about just this notion of the need to not overreach and not overthink what it is that you can do.” ID19  
13e “We know now that a big study has to be very simple.” ID12  
13f “My colleagues were proposing that we shouldn’t even test the behavioral intervention. They wanted to test use a sham intervention to test other components, such as recruitment, and blinding, and different factors. But I argued that I wanted to match the methods of the feasibility trial” ID5  |
| Failure to scale        | Combination of factors that blocked a larger scale trial based upon pilot results | 14a “The pilot studies did not go on to a full trial because the effects were not substantial enough, and not consistent enough.” ID3  
14b “The larger trial never materialized because we were unable to get funding. We just felt like the evidence wasn’t as convincing as we would have liked.” ID18  
14c “I wouldn’t take it forward to full trial because it just wasn’t well received. We didn’t get good engagement with clinicians and we struggled to recruit, despite spending a lot of time and a lot of resources.” ID15 |