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Reply

We appreciate the use of the magnifying lens by Fernandes, *et al*. to facilitate the understanding of the significance of clinical significance and type II errors in relation to our trial(1). Despite our best efforts we are however not convinced that their statistical arguments are relevant to the real clinical issues raised by the trial results and their interpretation. We hope our comments will alleviate their disappointment as well as their concern that a good idea may be discarded due to inappropriate interpretation of the p value.

Our trial(1) was designed to find out whether we could improve the UAC insertion time by using a magnifying lens. The 'superiority' design was based on our prior positive experience with the device and its safety and simplicity(2). It was also based on the fact that most clinicians would regard UAC insertion time 2-3 minutes as satisfactory. The desired 'clinically significant' improvement was clearly prespecified as reduction in UAC insertion time from 330 to 200 seconds (common std dev: 144, a priori power: 82%)(3). Given the dramatic improvement in the median insertion times (88 and 70 seconds) in both groups, the very purpose of conducting/continuing the study was defeated. The temptation to comment on the possible benefits of the lens to others ("soft advocacy") was best avoided and it was left to the readers to interpret the results and decide what may still be useful for them. Despite the tradition, the confidence interval (lens-no lens median difference: 18 seconds; 95% CI: [–89.49, 125.49] seconds) was not provided simply because the overall dramatic decrease in the insertion times made the original question about the magnifying lens clinically almost irrelevant(4). However, we did provide sufficient data to construct the 95% CI and more importantly the conditional power estimate of how likely were we to declare the superiority of the magnifying lens over the conventional method if the trial was continued.

The Hawthorn effect was indeed operational during our trial as indicated by the

active display of the photograph of an operator (UAC insertion time: 28 seconds) with a caption challenging others to beat the record. With time only the Hawthorne effect and not the operator variability are expected to diminish. Continuation of the trial was also not justified because our 'post-hoc' conditional power estimation showed that this was unlikely to detect any clinically significant benefit of the magnifying lens. The purpose of our discussion and conclusion was to focus on Hawthorne effect and operator variability–the two issues we faced in our trial. We have avoided definitive statements regarding the magnifying lens whether it should or should not be used. The key message and the abstract reflect purely what happened in the trial and should be read only in the context of the trial. The fact that this simple and safe device could still be useful for others reflects the realism in evidence-based medicine that relegates statistical analysis to its proper subsidiary place.

In summary we feel that being too close to the magnifying lens has blurred the real issues of clinical significance (operator variability and Hawthorne effect) in this case. We hope our observations will help in designing better clinical trials in this area while appreciating the fact that even the best randomized controlled trial will only minimize but not eliminate uncertainty.

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Street Children and Runaway Adolescents in Iran

With reference to the Editorial by Sethi(1) in the March issue of the journal regarding "Street Children", We would like to mention some points on the same issue in Iran.

Risky behaviors of the out-of-school children have been ignored in Iran, and it was only recently that the school students received due attention by the Ministry of Education(2). The growing number of runaway adolescents (especially girls who are more vulnerable to sexual abuse than boys) has urged the authorities to look for a systematic approach to a possible solution. However, dealing with the out-of-school children seems to be much more demanding than those in schools. Lack of reliable statistics on the real number of