AKI (74.5 minutes) [1]. If we consider all children, mean time between bite and ASV administration was 51.2 minutes. Moreover, many of the children received the first dose of ASV at the place of initial medical care, before referral to our center. The study referred to by the readers was conducted in 2012-2016 and included both children and adults [3]. Due to the sustained awareness campaigns and easy availability of ASV, bite to needle time is gradually decreasing. Transport vehicles are also easily available for children under different government schemes. Moreover, our study included children with viper-bite only, which is symptomatic at early stage leading to early seeking of healthcare.

KAMIRUL ISLAM
Department of Pediatrics, Burdwan Medical College, Burdwan, West Bengal, India.
kamirul.islam7@gmail.com

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Response to Journal Club: Cluster Randomized Trial Evaluating Impact of a Community-based Microfinance Scheme on Childhood Nutritional Status: Evidence-based Medicine Viewpoint

We read, with interest the Evidence-based medicine viewpoint [1] on our recent publication [2]. The author of the viewpoint has made some notable points about the methodology, most of which were already acknowledged in our paper. The viewpoint includes some interesting observations that appear to be based on selective use of the data and has some key errors, which we wish to highlight.

(*i*) *"Although a research question was not articulated…*" The study hypothesis is clearly stated in the last sentence of the introduction.

(*ii*) *"The investigators chose a cluster RCT design… It is difficult to judge which of the two designs is superior to compare community effects through individual empowerment of some members…"* A cluster randomized design is the appropriate approach when the intervention is delivered at the level of the local population (*tola*). Individual randomization is not possible when the intervention is delivered to a group (the self-help group).

(*iii*) *"The investigators used a computer program for randomizing pairs of tolas, although since only two tolas were randomized at a time, simple coin tossing is sufficient. Paired randomization obviated the scope for allocation concealment…"* There was complete allocation concealment as the *tola*s were assigned a code number and randomization took place in Nottingham with the local trial team informed only after randomization had taken place. Having the local team toss a coin would of course prevent allocation concealment.

(*iv*) *"It is also unclear what proportion of the children whose baseline data were collected, underwent data collection at the end of the study."* This is stated in table 2 of the paper *e.g.* of 1377 children with baseline data for WHZ, 559 were followed up longitudinally with further data at 18 months [2].

(*v*) *"First, it assumes that under natural circumstances, children's nutritional status declines over time. However, the authors showed no data supporting this presumption."* Nutritional indices deteriorated amongst children in both arms of the trial and this is a large sample. In these rural communities in Bihar, we have shown that nutritional status does decline over time.

(*vi*) *"…analysis of the reasons for taking loans in the Intervention arm shows that a very small proportion was used for food and supplies (in terms of percentage as well as absolute amount)."* On referring to figure 3 of the paper [2], we see that two of the top three reasons for taking loans were medical expenses and working capital for agriculture. Both of

these expenditures will have increased resilience to food insecurity.

(*vii*) *"It should be remembered that children in the Intervention arm had superior HAZ than those in the Comparison arm."* Nutritional disadvantage was seen in both the intervention and control groups at baseline - significantly more children were wasted in the intervention arm (20%) *versus* controls (15%).

(*viii*) *"However, the proportion of participating women in each tola were not described, hence this assumption could be too simplistic."* This is clearly stated in the online supplement (which is signposted in the main manuscript). *"In the intervention group, 35% of women overall (median by tola 37%, IQR 8% - 59%) reported being members of a Rojiroti SHG. In control tolas, 29% of women overall (median by tola 24%, IQR 0% - 54%) reported being a member of a non-Rojiroti SHG."*

We acknowledge that childhood malnutrition is a multi-factorial problem but the link between social and economic well-being and health is well documented. A multi-sectoral approach that addresses all the determinants (such as social, economic, cultural, and commercial) of child health and wellbeing is key to the integrated approach to health as promoted by the UN Sustainable Development Goals [3]. Our study is the first randomized controlled trial that focused on the effect of microfinance on child health [4]. Despite its limitations, it is a vital step toward achieving this joined-up thinking. The abovementioned shortcomings in the viewpoint [1] undermine the assertion that *"…it is difficult to draw firm conclusions from this trial or recommend further similar studies."* On the contrary, we believe the time is now right for scaling up the program within Bihar and neighboring states, whilst evaluating the intervention in settings where cultural practices, climate and agriculture differ.

SHALINI OJHA[1] AND ALAN R SMYTH[2]*

[1]Division of Medical Sciences and Graduate Entry Medicine and [2] Division of Child Health, Obstetrics & Gynaecology, University of Nottingham, Nottingham, UK.

**smyth@nottingham.ac.uk*

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AUTHOR'S REPLY

I thank the authors of the article [1] for their interest in our journal club discussing the same [2]. The points raised by the authors are based on selective interpretation of their own data [1] and selected quotes from the Evidence-based viewpoint [2]. Hence, none of the points change anything in the critical appraisal commentary [2]. Responses to specific points in the correspondence are as follows:

(*i*) 'Study hypothesis' is not synonymous with 'Research question'. Besides the fact that the latter includes five elements of the PICOT frame-work, it starts from a position of clinical equipoise (*i.e.* the investigators do not pre-assume that the intervention will be beneficial). Thus the 'Research question' sets the tone for the methods used in a study, and is a touchstone for readers/appraisers to judge its validity. It has been previously pointed out that the "science of evidence-based medicine hinges on the art" of framing appropriate questions [3].

(*ii*) It has already been emphasized [2] that a cluster RCT is the ideal design when either the intervention or outcomes or both, are expected to spill over into/onto those who are not randomized (but are present in the cluster). In this study [1], it is difficult to judge *a priori* whether the intervention (microfinance scheme support to individual women in certain households in a cluster) or outcome (nutritional parameters in their offspring) could have a spill-over effect on mothers (who did not receive the financial support) or their offspring, in which case an individually randomized trial would be more appropriate.

(*iii*) The study [1] mentioned that "*tola*s of similar size were paired" and those "in each pair were randomly assigned". For instance, if *tola*s 'A' and 'X' were paired and one of these was randomly assigned to a group, it follows that the other member of the pair would have to be assigned to the other group. This precludes any scope for allocation concealment. Thus one member of the pair would have a 50% chance of being assigned to either group, whereas the second member would have a 100% chance of being assigned to the other group. This is akin to using a coin-toss to randomize a pair of participants.

(*iv*) In this study [1], not all children who were present at