- 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 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 OJHA¹ AND ALAN R SMYTH^{2*}

¹Division of Medical Sciences and Graduate Entry Medicine and ² Division of Child Health, Obstetrics & Gynaecology, University of Nottingham, Nottingham, UK. *smyth@nottingham.ac.uk

REFERENCES

- Mathew JL. Cluster randomized trial evaluating impact of a community-based microfinance scheme on childhood nutritional status: Evidence-based medicine viewpoint. Indian Pediatr. 2020;57:459-63.
- 2. Ojha S, Szatkowski L, Sinha R, Yaron G, Fogarty A, Allen SJ, *et al.* Rojiroti microfinance and child nutrition: A cluster randomised trial. Arch Dis Child. 2020;105:229-35.
- Coll-Seck A, Clark H, Bahl R, Peterson S, Costello A, Lucas T. Framing an agenda for children thriving in the SDG era: A WHO-UNICEF-Lancet Commission on Child

- Health and Wellbeing. Lancet. 2019;393:109-12.
- Gichuru W, Ojha S, Smith S, Smyth AR, Szatkowski L. Is microfinance associated with changes in women's wellbeing and children's nutrition? A systematic review and meta-analysis. BMJ Open. 2019;9:e023658.

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 "tolas of similar size were paired" and those "in each pair were randomly assigned". For instance, if tolas '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

baseline were available for follow-up at 18 months; and not all children whose 18 month data were collected, had data collected at baseline. Thus, children whose data were collected at 18 months of age (presented in table 2 of the article) [1], comprised an unknown proportion of those who were present at baseline, plus an unknown proportion of those who were not present at baseline.

- (v) The authors [1] found that children in the comparison group fared worse than children in the intervention group. Notwithstanding the methodological limitations compromising validity, they assumed this to mean that under natural circumstances, nutritional status of children would decline, and the intervention partially mitigated this. But they have not provided any data from any study, anywhere in the world, that can support this view. This suggests that the explanation offered for the unusual finding in this study [1] is erroneous. This view is strengthened by the other points mentioned in the commentary [2].
- (vi) Figure 3 in the study [1] shows that only about 12% of the loans were for 'food and supplies' and the total amounted to less than Rs. 10,000 across the *tolas*. In the face of food insecurity (*i.e.*, starvation), one would expect people to take loans to purchase food (to tide over the immediate scarcity) rather than invest in capital for agriculture or medical supplies (that have no short-term impact on starvation).
- (vii) The table of baseline characteristics in the study [1] showed statistically significant differences in three anthropometric parameters between the intervention and comparison groups. Two of these were better in the intervention group viz HAZ (Z score -2.00 vs 2.14) and proportion with MUAC <12.5 cm (13% vs 16%). In contrast, the proportion with wasting was higher in the intervention group (20% vs 15%). These data suggest that children in the intervention group

had (statistically) better HAZ. Since height Z score is an indicator of longer-term nutritional status and does not decline immediately in acute malnutrition (unlike wasting or MUAC), it suggests that children in the interventional group had a statistically superior indicator of longer-term nutritional status (at baseline).

(viii) Since only one-third of the mothers in the intervention group actually received the intervention, it is difficult to believe that the comparable outcomes in offspring of those who did (and did not) receive the intervention was based on a spillover effect. The authors have not demonstrated how/why financial empowerment of a limited number of women in the community could create a spillover effect to other mothers and families.

In summary, methodological limitations compromise the validity of the trial [1], and the authors' recent comments do not change the viewpoint that this trial is insufficient to support further similar studies or launch a community-wide intervention with the specific microfinance scheme described (for the purpose of improving nutritional status of children). Whether the scheme could have any other positive social or cultural or health-related impact, is outside the scope of discussion.

JOSEPH L MATHEW

Advanced Pediatrics Centre, PGIMER, Chandigarh, India. dr.joseph.l.mathew@gmail.com

REFERENCES

- Ojha S, Szatkowski L, Sinha R, Yaron G, Fogarty A, Allen SJ, et al. Rojiroti microfinance and child nutrition: a cluster randomised trial. Arch Dis Child. 2020;105:229-35.
- Mathew JL. Cluster randomized trial evaluating impact of a community-based microfinance scheme on childhood nutritional status: Evidence-based medicine viewpoint. Indian Pediatr. 2020;57:459-63.
- 3. Mathew JL, Singh M. Evidence based child health: Fly but with feet on the ground! Indian Pediatr. 2008;45:95-8.

Acute Peritoneal Dialysis in Premature Infants: Few Concerns

We read with great interest the recent article by Okan, *et al.* [1] published in *Indian Pediatrics* which concluded that peritoneal dialysis (PD) is technically feasible in very low birthweight (VLBW) and extremely low birthweight

(ELBW) neonates despite a high mortality rate in the studied population (81%). We also agree that peritoneal dialysis in neonates, and particularly in preterm neonates, is challenging and is still evolving with only few anecdotal case report and case series till date indicating its feasibility in preterm neonates. Further, due to the physiological compromise (small size, poor hemodynamic stability and tendency of coagulopathy), overall prognosis in preterm neonates undergoing peritoneal dialysis is grimmer as compared to their term counterparts as well as older