Interim report for granted project

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Title of the granted project	Levonorgestrel-Intrauterine System (LNG-IUS) and Copper Intrauterine Device Insertion in the Postpartum Period: a Pilot study
Amount granted by the ESC (in euro)	4532
Initial funding (part of the grant received already) in euro:	3400
Final amount to be paid by ESC (in euro):	1132
Project number:	P-2015-B-05
Allocated mentor:	B. Zilaitiene
Date project actually started:	01-04-2016
Planned date of completion:	30-11-2017
Have there been any problems or issues with starting or continuing this project? If so, what impact will that have on your planned completion date?	The project has been implemented through 2 rural health centres of Action Research & Training for Health (ARTH), in Rajasthan, India. Some preparatory activities were carried out in April to June 2016, including development of research plan, development and translation of project tools, ethical review and orientation of service delivery staff. a. The data collection could start in August 2016, instead of July 2016, that was originally planned, since the nurse midwives were not trained in technique of PPIUCD insertion. For hands-on training, we had to send nurses to a Government medical college, where large numbers of PPIUCD insertions take place. However, seeking permission for this training took time, hence the data collection for study could start in mid-August 2016. b. Since the nurses had just learnt the technique of PPIUCD insertion, they were extra cautious in the first 1-2 months, hence the number of insertions was low in the first month. Now we have achieved 29 insertions, and in order to complete 12 month followp-up of these women, we will need time upto November 2017, this will mean the project completion date will be Dec 2017 (three months later than the originally planned date of Sep 2017). c. Because the amount of funding approved for this project was 4532 Euros (as against 9065 that we applied for), we had to reduce the sample size to 30 instead of 50 that was proposed earlier. We are seeking funding for a full scale trial on same trial.
Have you discussed the project status and any problems with your Mentor?	Yes

Please provide a synopsis of your findings and data so far (max 500 words)	The progress of the project has been as follows: 1. All nurses and doctors were provided a one day orientation in June 2016, on the project, its objectives and methodology. 2. Development of research plan and questionnaires: During April - June 2016, a research plan (study protocol) and questionnaires were developed. 3. Ethical application, development of consent form: The study was approved by Ethical Review Committee of ARTH. 4. Training of nurse-midwives on PPIUCD insertion was carried out on 5 days in August 2016 in Government Medical College in Udaipur. 5. Starting of data collection: Random number list was generated, and opaque sealed envelopes with random numbers were sent to two clinics. The staff started counseling women in antenatal clinics about the study and seeking their consent. A post-delivery checklist was used to again assess their eligibility and willingness, after delivery. In the two arms, LNG-IUS or copper IUD (CuT 375) were used. The data collection started on 10th August onwards. 6. Quality supervision and monitoring was done by project director and research supervisor. 7. Till 15 November 2016, a total of 29 insertions had been done. It is expected that by end of November, 30 insertions will be completed. 8. Follow-up at 8 weeks had been done for majority of women who have complete 8 months (for 81% women).
Please provide a current budget on how much you have spent to date. Receipts may be requested.	Approved (in Euro): 4532 Expenditure (in Euros): Salary- Project investigator 3300 Service delivery support to provide IUD LNG-IUS: 338 Printing of research forms , instruction sheets etc. 14 Institutional overheads 0 Total expenditure (in Euro): 3652
Add any other information you feel we should have at this stage.	Meanwhile, we are seeking additional funding for a full scope trial for this study involving 3 sites (in 3 states) in India. The experience of implementing this pilot will come in use for preparing a research plan for larger study.
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