








RESEARCH ARTICLE

REVISED **Module intervention to improve involvement and practices of fathers towards infant and young child feeding (IYCF) in Coastal South India - a randomized controlled trial [version 2; peer review: 3 approved]**

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Abstract

Background: Overall child health depends on nutrition and its related practices. At the family level, responsibility of child feeding lies with both parents. There is no uniform and systematic way to determine and assess the practices of fathers in infant and young child feeding (IYCF). Also, there is a paucity of evidence related to interventions for fathers in improving their practices and involvement in the feeding of their infant or young child (aged less than two years).
















Methods: This was a community-based randomized control trial, conducted among 120 fathers with infants and/or young children in Dakshina Kannada District of Karnataka. Fathers with poor level of involvement and practices towards IYCF, during the initial assessment, were included as the study participants. For the intervention, a module in the flipchart format was developed. Simple randomization technique was used to allot the participants into two groups - intervention and control. Participants in the intervention group received module intervention, in addition to the care which they received routinely, and the control group received only routine care. The participants in the intervention group were paid a monthly visit to implement the module, for six months. The post-intervention assessment was done at the end of 6 months.




Results: A total of 117 participants provided post-intervention data. The mean age was 34.7 (+/- 5.48) years in the intervention group and 34.36 years (+/- 5.26) in the control group. The intervention group showed significantly higher improvement in knowledge, attitude, and practice components at 6 months ($p < 0.05$), in both unadjusted and adjusted models.

Conclusions: The extent of increase in practice and involvement in

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Any reports and responses or comments on the article can be found at the end of the article.

child feeding was clearly higher among the intervention group. The module developed was successful in improving the practices of fathers in feeding their infants and young children.

Clinical Trials Registry India: CTRI/2017/06/008936 (29/06/2017)

Keywords

Paternal, IYCF, involvement, module, trial



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REVISED Amendments from Version 1

Revisions were made to the abstract, introduction, methodology, results, and discussion sections based on the comments and suggestions made by the reviewers. In the introduction section, information was updated and justification for the need for the study was stressed. In the methodology, revised analysis was performed based on the reviewer inputs and text updated accordingly; followed by results and discussion.

Any further responses from the reviewers can be found at the end of the article

Introduction

The health of the children reflects the overall health of a community and country. However, child health is affected and influenced by several factors such as nutrition and feeding practices in the early months of life. These are also important determinants of children's health, growth, and survival.^{1,2} Although the responsibility of a child's feeding lies with both the parents, much of the emphasis and stress has been on mothers. Several cultural and traditional factors restrict or limit the participation from the fathers. When both parents put their efforts together for the child's feeding practices, the child has a higher chance of receiving better nutrition.³⁻⁶

The important role and influence that fathers can have in shaping their children's eating patterns have been documented.⁷ Paternal feeding practices towards their young children also reflect the way of time management done by the fathers.⁸ Despite this established paternal role in child-rearing, most of the research and policies related to child feeding, have not given importance to fathers.^{9,10} Also, in real life situations, occupation or other family related factors make the fathers skip major aspects of childcare, especially feeding practices. Several strategies using media, healthcare providers, and peer-to-peer interventions have been implemented to improve child nutrition. However, all these were keeping mothers as main recipients.^{11,12} But support from the father of the child, coupled with a change in attitude and knowledge even at the stage of breastfeeding has given promising results in terms of the success of breastfeeding and overall nutrition of the child.^{11,13} However, in many instances, fathers possess the knowledge and positive attitude towards infant and young child feeding (IYCF), but it may not be reflected in their practices.⁶ Thus fathers of infants and young children need a reinforced information and communication in this regard.

Many factors have a role to play in determining the level and extent of paternal practices in infant and child feeding practices. Still, there is a paucity of evidence related to these practices.¹⁴⁻¹⁷ A simple, easily accessible and repeatable module for fathers would stimulate them to have better participation in the care of their infant or young child. This also could reinforce important factors which need special attention, like choosing weaning food, enhancing the consistency of food items as the child grows and maintenance of hygiene. Given the culturally diverse Indian population, no modular interventions for fathers to improve their IYCF practices have been evaluated so far.

Thus, this trial was carried out to develop and test the effectiveness of a module, targeting fathers with either infants or young children aged less than 2 years, in improving their involvement in IYCF.

Methods**Ethical issues**

Approval was obtained from the Institutional Ethics Committee (IEC) of Kasturba Medical College, Mangalore (approval number IEC KMC MLR 06-17/111 dated 21st June 2017). After obtaining the approval, data collection commenced. A participant information letter was provided and written informed consent was taken from each participant, after assuring anonymity and confidentiality for the information they provided. This article is reported in line with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.¹⁸

Trial design

This community-based open-label randomized controlled trial was carried out among 120 fathers of infants and young children aged 12 to <24 months in Dakshina Kannada District (Karnataka State), India, between January and December 2020. The sample size calculation, recruitment of study participants, sampling techniques followed, methodology of randomization, intervention procedures have been described earlier.¹⁹ The Template for Intervention Description and Replication (TiDier) was used for the description of the methodology.²⁰ Sample size for this trial was calculated using an assumption of 15% improvement in the paternal practices related to IYCF after module-based intervention, 80% power, 5% alpha-error, 1:1 allocation and adding 20% non-response error, as 60 participants in each group.

The eligible participants for this trial were selected using stratified multistage random sampling technique; wherein we did the stratification at subdistrict level. At each stratum, the health centers of the public health system were chosen using

simple random sampling done with the help of lottery technique, with probability proportionate to size, keeping the population covered by the centres as benchmark. Each center caters to several wards (administrative sub-unit) and again using lottery technique, a ward was selected from the health center area. From the health centers, we could collect the list of infants and young children in selected wards and visit their fathers who were selected using convenient sampling method, on a pre-approved, mutually convenient time in their houses. A total of 450 eligible fathers were assessed.²¹ The registration of this trial was done in Clinical Trials Registry- India (CTRI/2017/06/008936) on 29 June 2017.²²

Participants

The fathers with at least one infant or a child aged less than 2 years were eligible for inclusion in the initial assessment. After the initial assessment of the eligible fathers in their involvement in IYCF,²¹ they were classified as having either good or poor involvement in IYCF. This assessment included the knowledge, attitude and practice aspects of IYCF, in the form of an investigator administered questionnaire.¹⁸ In case of participants with more than 1 child, the domains were assessed as applicable to the youngest child. The questionnaire consisted of scores for each of the three above mentioned domains as five-point likert scale and the total scores for practice domain were computed. Since there is no pre-existing cut-off for the score, we chose to use the median score as the cut-off to determine the number of fathers with less than 50th centile practice score to depict poor involvement.

Those fathers with poor involvement were the eligible participants for this trial. Their list was arranged according to the Taluks (a sub-District administrative unit in India) of their residence and simple random sampling was used to select the Taluks. The participants from each of these Taluks were selected using simple random sampling. A total of 130 eligible participants were approached to meet the target sample size of 120. They were visited and explained about the objectives and nature of the intervention in the local language. In total, 10 eligible participants declined the invitation. Written informed consent was taken from all the participants who agreed to be part of this trial. The selected fathers were randomized into intervention & control groups. We used simple randomization technique with lottery method, using Microsoft Excel software. The generated sequence was converted to 120 opaque containers and arranged by principal investigator (PM). Another author (NK) performed sequential enrolment of participants. Following this, third author (RT) ensured the assignment of participants to the appropriate interventions. Final implementation of the intervention was done by research assistants.

Outcomes

Baseline and post-intervention assessments at the end of 6 months were done using a content validated questionnaire, which included demographic component, awareness, attitude, and practices related to IYCF. This questionnaire was developed by the authors and tested for internal consistency along with inter-rater reliability. We used Cronbach alpha for internal consistency and correlation for validity for the domains of knowledge, attitude and practices. Minor revisions were then done to reach acceptable level of reliability. The questionnaire and other intervention materials can be found as *Extended data*¹⁸. At the end of 6 months, due to the coronavirus disease 2019 (COVID-19) pandemic lockdown situation, the post-intervention assessment was conducted over the telephone and google form-based blended approach due to the inability to travel to the field and to avoid personal contact with the participants.

Intervention procedure

For the intervention arm, the IYCF module was developed towards the improvement of paternal involvement in IYCF, as a pictorial-explanation flip-chart form based on extensive literature review and existing knowledge in the field.¹⁸ The module included information on feeding the baby from the time of birth, ways in which a father can support the mother in breastfeeding, significance of paternal decision in child feeding practices, when and how weaning has to be started for the baby and ways of father's involvement in general childcare. This information was in the form of bulleted points and supported by relevant images. For e.g., exclusive breast feeding and how fathers can help the mothers in this practice; food items not recommended for infant feeding; food items to be included during weaning etc. The IYCF module was implemented in Kannada (the local language) after it was pilot tested for operational feasibility. Pilot testing was done in the field among five fathers with poor involvement in IYCF, but not part of the main trial. The interactions were documented, difficulties in communications, usage of terms were addressed. Also, feedback was taken from the participants. Finally, revision of the module was undertaken.

The intervention was done by two research assistants from the Medical Social Work background, who were trained in implementing the module in the community. They visited the participants on pre-informed dates at their homes or a convenient location and at a convenient time. The module in the flip-chart mode was implemented to the intervention arm on a one-to-one interaction basis. [Figure 1](#) depicts the components and important aspects addressed in the module. The participants had a look at the pictures in the flip-chart to start the interaction, accompanied by the explanations by research assistant. This was followed by the rotation of the flip chart to get the view of the same points in sentence format.

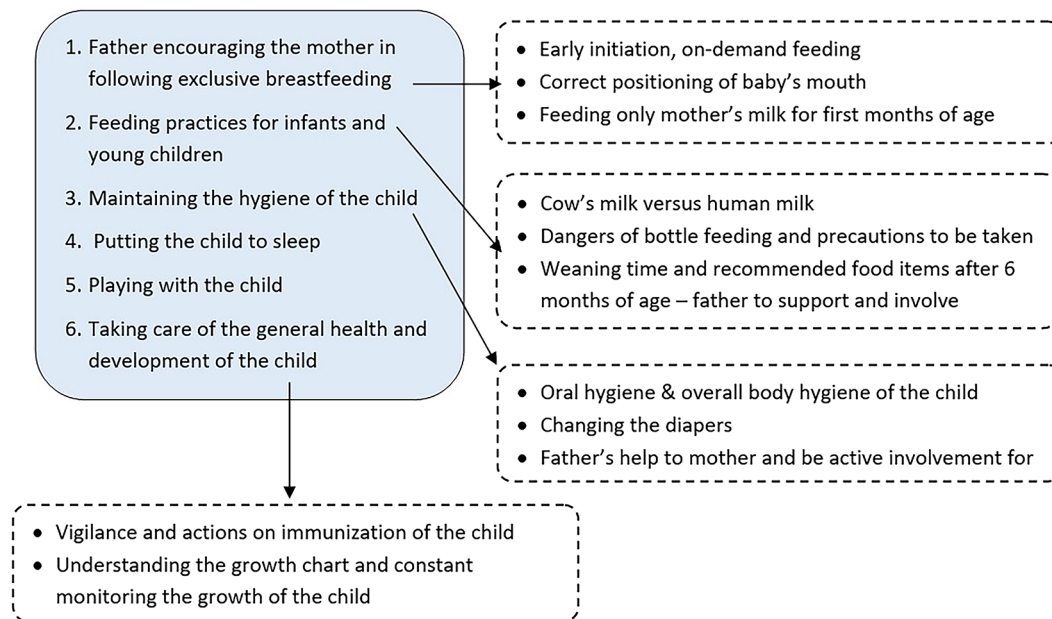


Figure 1. IYCF module components.

This process was done for all components of the module. Each interaction lasted for 20 to 30 minutes including the question-and-answer sessions. During this interaction, only the participant father was present along with the research assistant, to avoid any intervention contamination. The administration of the same module was done once a month for 6 months. Participants in the control group received their regular care in the health centers, whenever they visited with their child and during regular visits to them by the health workers.

Data analysis

We analyzed the data using **IBM SPSS Statistics** for Windows, Version 25.0 (RRID:SCR_016479). Data management was done at the central coordinating site, located in the study institute. Results were arranged as proportions, mean (with standard deviation) using the tables. Individual scores of knowledge, attitude and practice components were added from the Likert scale response of each component and a total score was obtained. These total scores were used to compare the intervention and control groups.

The comparison for the knowledge, attitude, and practice scores across the groups was done using chi-square test, paired & independent sample 't' tests. Intention to treat analysis was followed. Imputation method was used to derive the missing variables for lost to follow up participants. Cohen's 'd' (with 95% confidence interval) was calculated to estimate the effect size for the intervention. An estimate of more than 0.8 was considered as large effect. For the comparison of effects of intervention on final outcomes after adjusting for covariates spread unequally across intervention and control arms, mixed effects linear regression model was used. The models were constructed with knowledge, attitude and practice post intervention scores as dependent variables, each with fixed effects of time (baseline), age and education, along with random effects of occupation and baseline knowledge. Also, the interaction of these covariates on the outcome was assessed. For mixed effects linear model, F value and partial eta square (η^2) were reported. A p-value <0.05 was considered statistically significant.

Results

In total, 130 fathers were assessed for eligibility of which 120 were randomized. All the selected participants who were randomized into the intervention arm, attended one session per month for six months to complete the modular interventions. However, for the post intervention outcome assessment, two participants in the intervention and one in the control group could not be accessible after several attempts to provide follow up information on IYCF practices. Finally, 117 participants (n=58 for intervention, n=59 for control) completed the outcome assessment.¹⁸ The flow of study as per the CONSORT format is provided in **Figure 2.**^{23,24}

The mean age of the intervention group was 34.7 (± 5.48) years and the control group was 34.36 years (± 5.26) (p=0.711). Both the study groups were similar concerning their demographic characteristics (age group, educational

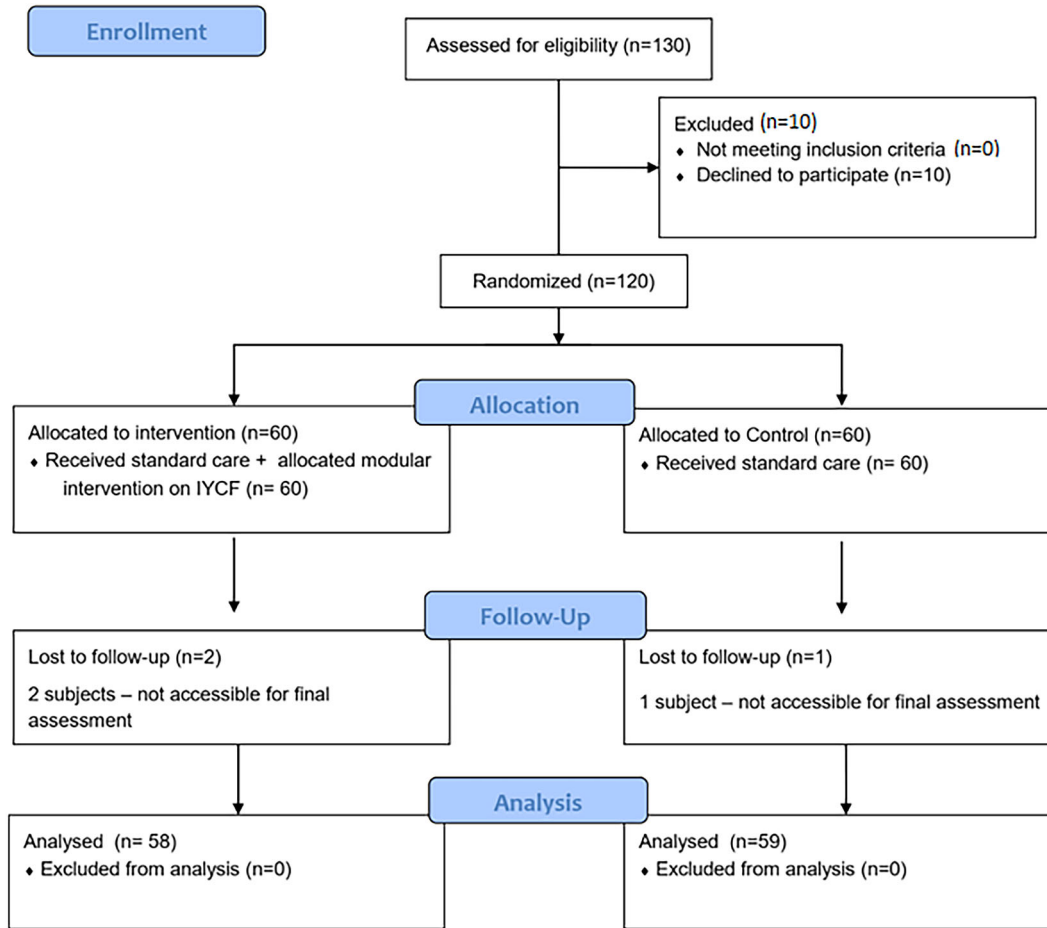


Figure 2. Study CONSORT diagram. IYCF=Infant and Young Child Feeding.

Table 1. Baseline characteristics of the study population (N=120).

Characteristics		Intervention group (n=60) No. (%)	Control group (n=60) No. (%)	p-value
Age group (years)	</=30	13 (21.7)	19 (31.7)	0.49
	31-40	38 (63.3)	34 (56.7)	
	>/-41	09 (15.0)	07 (11.6)	
Educational status	Less than high school	23 (38.3)	29 (48.3)	0.39
	Completed high school	22 (36.7)	14 (23.3)	
	Pre-degree	06 (10.0)	07 (11.7)	
	Graduation and above	09 (15.0)	10 (16.7)	
Occupation	Unskilled	07 (11.6)	18 (30.0)	0.03*
	Semiskilled	13 (21.7)	16 (26.7)	
	Skilled	31 (51.7)	22 (36.7)	
	Professional	09 (15.0)	04 (06.6)	
Parenthood	First-time fathers	24 (40.0)	32 (53.3)	0.16
	Experienced fathers	36 (60.0)	28 (46.7)	
		Mean (SD[#])	Mean (SD[#])	
Age (Years)		34.70 (5.48)	34.36 (5.26)	0.71
Knowledge score		55.35 (6.58)	60.03 (2.28)	<0.0001*
Attitude score		15.85 (2.46)	16.37 (1.29)	0.19
Practice score		30.95 (1.35)	30.71 (3.89)	0.39

*p-value significant at 0.05 level.

[#]SD=Standard Deviation.

Table 2. Comparison between baseline and post-intervention scores across the study groups.

	Intervention group (n=60)				Control group (n=60)				p-value
	Baseline Mean (SD)	Post-intervention Mean (SD) (Unadjusted)	Post-intervention Mean (SD) (Adjusted)	p-value	Baseline Mean (SD)	Post-intervention Mean (SD) (Unadjusted)	Post-intervention Mean (SD) (Adjusted)	p-value	
Knowledge score	55.35 (6.58)	80.32 (2.30)	80.95 (1.11)	<0.0001*	60.03 (2.28)	52.43 (9.88)	51.78 (0.99)	<0.0001*	
Attitude score	15.85 (2.46)	18.24 (1.29)	18.37 (0.22)	<0.0001*	16.37 (1.29)	16.99 (1.86)	16.89 (0.22)	.061	
Practice score (involvement in IYCF)	30.95 (1.35)	49.80 (4.10)	50.01 (0.96)	<0.0001*	30.71 (3.89)	34.25 (8.57)	33.97 (0.94)	.005*	

*p-value significant at 0.05 level.

#SD=Standard Deviation, IYCF=infant and young child feeding.

Table 3. Comparison of change scores across the two study groups (N=117).

	Intervention group Mean (SD)	Control group Mean (SD)	p-value
Knowledge score	24.89 (0.88)	-7.61 (1.41)	<0.0001*
Attitude score	02.38 (0.38)	0.61 (0.32)	0.001*
Practice score (IYCF involvement)	19.10 (0.54)	3.17 (1.08)	<0.0001*

*p-value significant at 0.05 level.

*SD=Standard Deviation, IYCF=infant and young child feeding.

status, being first-time father or experienced father, attitude, and practice scores). The two groups were significantly different concerning the occupation categories and knowledge scores ($p=0.03$ and <0.0001 , respectively) at the baseline (Table 1).

The before and after comparisons of the scores are described in Table 2. Post intervention mean scores were adjusted for occupation and baseline knowledge scores which varied across intervention and control arms. The intervention group showed statistically significant ($p<0.0001$) improvement in all three scores, i.e., knowledge, attitude and practice scores. In the control group, there was a decline in the knowledge scores at 6 months. We found this difference to be statistically significant ($p<0.0001$).

The mixed effects linear regression model showed significant treatment effect for knowledge, ($F_{(1, 113)}=59.6$, $\eta^2=0.35$, $p<0.0001$), attitude $F_{(1, 113)}=11.1$, $\eta^2=0.9$, $p=0.001$ and practice (IYCF involvement) ($F_{(1, 114)}=16.68$, $\eta^2=0.13$, $p<0.0001$) across the intervention and control arms. (η^2 – partial eta squared). However, the covariates – occupation of the participants and baseline knowledge on IYCF had no significant main effects on any of the three domains assessed. Also the interaction of these covariates was not found to be statistically significant. On knowledge, the interaction was $F_{(2, 113)}=0.33$, $p=0.72$, on attitude - $F_{(2, 113)}=1.64$, $p=0.98$ and on practice – $F_{(2, 114)}=0.23$, $p=0.79$.

There was also improvement in the attitude; however, the difference was not found to be statistically significant ($p=0.061$). Also, there was a statistically significant improvement in practice scores in the control group ($p=0.005$). When the change scores were compared across the two groups between pre-intervention and post-intervention scores, all the three change scores (knowledge, attitude and practice) were higher for the intervention group. These differences were found to be statistically significant ($p<0.0001$). The details of the change score comparisons are given in Table 3. The correlation test between change scores of knowledge and practice aspects of IYCF revealed significant association. Further, the estimation of effect size (Cohen's 'd') revealed large effects for the change scores of all the three components across the intervention arms. The estimate for knowledge domain was 1.75 (95% CI: 1.57-1.92), attitude 0.65 (95% CI: 0.31-0.99) and practice domain 1.54 (95% CI: 1.32-1.78).

Discussion

Father's support can greatly improve the status of mother and child health in the community, by bringing positive change in feeding practices of children right from birth.⁵ Also, the fathers' parenting skills, feeding practices may the nutritional behaviour and overall growth and development of the child.^{9,25,26} Although, because of several changes in society, fathers' involvement in childcare has been witnessing an upward trend over time, it is still influenced by a multitude of factors.^{5,7,27} Being a father is challenging in terms of overall childcare and the child's diet.²⁸ These challenges could be in terms of influence of other elderly family members in deciding the IYCF, lack of experience in childcare, absence of felt need of their involvement and many hidden factors. Neha Khandpur *et al*, in 2014, in their systematic review, reported that feeding practices varied in mothers and fathers. Fathers' feeding practices towards children contributed significantly to the nutritional status of children.⁹ This review also highlighted the shortage of literature and thereby information on child feeding practices of fathers. The current situation of limited fathers' involvement in IYCF and influencing factors have been reported in our earlier paper.²¹ We reported a 40.9% of fathers of infants or young children having poor involvement in IYCF and the same was higher among fathers belonging to urban area. Younger age and having education above graduation was associated with better involvement in IYCF. Occupation did not have a direct influence on involvement of fathers in IYCF. Also, these fathers had favourable attitude towards receiving education and training on handling babies and children, so that overall growth of their children would not be compromised.

Better paternal involvement in IYCF is possible with provision of adequate knowledge to the fathers of young children, in addition to prospective fathers.²⁷ Considering the current Indian scenario, wherein most of the child nutrition and care-related interventions have been focusing on mothers,²⁵ we developed a unique and simple father-oriented module.¹⁸

This module targeted an increase in knowledge, improvement in attitude and practices towards IYCF. As reported by Han *et al* in 2019,²⁹ behaviour change communication (BCC) strategies are important in enhancing involvement in child feeding. However, they also noted that only knowledge gain would have a limited impact on IYCF practices. They involved mothers of children along with fathers in their community-based trial.

In our trial, the group of fathers, after receiving the modular intervention in addition to the standard care, had significant improvement in knowledge, attitude and involvement towards their IYCF. Also, the control group which received standard care showed a decline in their knowledge, a mild increase in attitude, and a significant increase in practice. However, the change scores reflected a higher difference due to the implementation of this module. Several varieties of interventions have been tried, both in developing and developed parts of the world. A trial by Pisacane A *et al* in Italy, conducted in 2005 towards teaching the fathers on handling and managing lactational problems showed better breastfeeding practices till 6 months.¹¹ Similarly, Han *et al* in 2019,²⁹ assessed the impact of both-parent behavior change programs through communication on IYCF practices compared to the maternal program alone. They noted that father's IYCF knowledge increase was highest when it was clubbed with maternal BCC as compared to paternal BCC alone. However, they also reported that additional gain in knowledge did not translate to further enhancement in practices of IYCF. Elizabeth Sloand *et al* in Haiti³⁰ evaluated a public health nursing strategy using village-based fathers clubs. The post-intervention opinion from the participants revealed that childcare and health improved because of this intervention. A quasi-experimental study by Faith Thuita *et al*, in Kenya, in 2015, studied the impact of involving fathers and/or grandmothers on diets of mothers and IYCF practices in a rural setting and they found this model successful.¹²

There have also been attempts to enhance paternal involvement in IYCF, right from the antenatal period of their spouses. Jenny Tohotoa *et al* in Perth, Australia, in 2009, carried out antenatal sessions for fathers from different socio-economic strata and reported that a father-oriented approach was successful in terms of acceptance of the education material and involvement in baby feeding following the delivery of their spouse.²⁸ Bruce Maycock *et al* in Australia, in their fathers infant feeding initiative (FIFI Study), provided antenatal education sessions and postnatal support targeted to fathers and they reported that higher age and socioeconomic status of fathers had better breastfeeding rates.³¹

Another quasi-experimental study carried out by Abdullahi *et al*, in Somalia, in 2019, aimed at assessing the peer counselling effects by either mother or father as a support group on IYCF practices. They noticed a positive trend in knowledge, breastfeeding practices, and diet diversity among intervention arms.³² Shorey *et al* in Singapore in 2017, noted that enforcement of paternal involvement throughout the perinatal period by healthcare professionals had a positive response.¹⁷

In our study, we also noted that knowledge and practice scores showed higher change scores as compared to attitude scores in both the study arms. This could be due to pre-existing higher baseline scores related to attitude. However, the intervention arm has higher change scores. This could be further supported by the observation made in study which noted the decline in knowledge of control arm, which had a higher knowledge score at the baseline than intervention arm. All the previous studies showed improvement in paternal practices towards IYCF to a variable extent. However, the applicability to the wider population, the need for a professional to provide the interventions, and accessing the fathers at the right time have been some of the challenges faced by these studies. But the current module has been made simple to use by a grass-root level health worker and is made culturally neutral. Similar modular intervention-based approaches could be implemented in wider populations. The current study was carried out in a District which is having high literacy rates and better health-seeking behaviors. Thus, further effects in other regions of the country and outside regions remain to be tested. Also, the long-term effect of this module intervention, which could not be assessed in this study, would signify the need for re-enforcement of relevant information on paternal involvement in IYCF. Consequently, it would benefit the health care practitioners and policymakers in improving child growth and development through the strengthening of paternal involvement in IYCF and suitably planned interventions.

Conclusions

The participating intervention and control groups were similar to each other concerning most of the demographic characteristics. Both the groups had significant improvement in attitude and practice components at the end of 6 months, but the change scores were significantly higher for the intervention group. Also, concerning knowledge related to IYCF, the control group had a decline, and the intervention arm showed significant improvement. Thus, the module developed was successful in improving the overall involvement of fathers in their infant and young child feeding.

Data availability

Underlying data

Open Science Framework: Effectiveness of a module-based intervention on paternal involvement in Infant and young child feeding (IYCF) practices in Coastal South India - A Randomized Controlled Trial. <https://doi.org/10.17605/OSF.IO/D9GZ5>.¹⁸

This project contains the following underlying data:

- RCT final with all raw data.xlsx (this dataset includes the compiled scores in knowledge, attitude and practice domains at baseline and post-intervention; 1A1-1C14 reflect pre and 2A1-2C14 reflect post intervention data)

Extended data

Open Science Framework: Effectiveness of a module-based intervention on paternal involvement in Infant and young child feeding (IYCF) practices in Coastal South India - A Randomized Controlled Trial. <https://doi.org/10.17605/OSF.IO/D9GZ5>.¹⁸

This project contains the following extended data:

- CONSORT-Final-RCT.png (CONSORT flowchart)
- Informed consent-F1000.docx (Participant information sheet and consent form)
- IYCF module.pdf (intervention material)
- Questionnaire-F1000.docx

Reporting guidelines

Open Scientific Framework: CONSORT checklist³³ for 'Module intervention to improve involvement and practices of fathers towards infant and young child feeding (IYCF) in Coastal South India - a randomized controlled trial'. <https://doi.org/10.17605/OSF.IO/D9GZ5>.¹⁸

Data are available under the terms of the [Creative Commons Attribution 4.0 International license](https://creativecommons.org/licenses/by/4.0/) (CC-BY 4.0).

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Reviewer Report 12 July 2022

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Sathish Thirunavukkarasu 

Dept. of Family and Preventive Medicine, Emory University, Atlanta, GA, USA

Thank you authors for addressing my comments satisfactorily.

Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 12 July 2022

<https://doi.org/10.5256/f1000research.135364.r143258>

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Amutha Ramadas 

Jeffrey Cheah School of Medicine and Health Sciences, Monash University Malaysia, Bandar Sunway, Malaysia

I am satisfied with the changes made to the paper based on previous feedback.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Nutrition

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 07 July 2022

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Elezebeth Mathews 

Department of Public Health and Community Medicine, Central University of Kerala, Kasaragod, Kerala, India

I have reviewed the manuscript. Authors have addressed the comments and articulated it satisfactorily in the manuscript. The version 2 of the manuscript may be accepted for indexing.

Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 15 June 2022

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Amutha Ramadas 

Jeffrey Cheah School of Medicine and Health Sciences, Monash University Malaysia, Bandar Sunway, Malaysia

Overall, the manuscript is clearly written for comprehension of the scientific community. The title and abstract reflected the content of the manuscript.

I believe the article may benefit from the following input:

1. Introduction is brief and should provide more in-depth background info and justification for the research gap.
2. Methods - The flow is clear, and ethics approval and sample size justification have been provided. However the intervention may need to be described further, perhaps with some examples of the materials used.

3. Results - I have a concern with the significant difference in occupation status between groups, which could have impacted the results but was not adjusted for when the main outcomes were compared.

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?

Partly

If applicable, is the statistical analysis and its interpretation appropriate?

Partly

Are all the source data underlying the results available to ensure full reproducibility?

No

Are the conclusions drawn adequately supported by the results?

Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Nutrition

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 20 Jun 2022

Prasanna Mithra, Kasturba Medical College, Mangalore, Manipal Academy of Higher Education, Manipal, India

Reviewer Comments; followed by the response (in bold) by Authors:

Overall, the manuscript is clearly written for comprehension of the scientific community. The title and abstract reflected the content of the manuscript. I believe the article may benefit from the following input:

Introduction is brief and should provide more in-depth background info and justification for the research gap.

Thank you for the valuable input and suggestions. The "Introduction" section is now revised to add relevant points as suggested and background information is made

more robust. A stronger justification for the research gap is now added.

Methods - The flow is clear, and ethics approval and sample size justification have been provided. However the intervention may need to be described further, perhaps with some examples of the materials used.

Thank you. We have now revised the text related to the intervention procedure. Have added more details on the module and added examples at relevant places as per the suggestion.

Results - I have a concern with the significant difference in occupation status between groups, which could have impacted the results but was not adjusted for when the main outcomes were compared.

Thank you for the suggestion. We have now relooked into the analysis part based on the comments of the reviewers and have adjusted for the baseline differences to report the outcomes. Both the adjusted estimates and effect of interactions have been reported.

Competing Interests: No competing interests were disclosed.

Reviewer Report 24 May 2022

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Elezebeth Mathews 

Department of Public Health and Community Medicine, Central University of Kerala, Kasaragod, Kerala, India

Authors have rightly identified the research gap of paternal involvement in child care and nutrition. This was a randomized controlled trial to enhance the involvement of fathers in infant and young child feeding practices among those fathers identified to have poor involvement in child care in Dakshina Kannada District. The authors have described the methodology clearly in this manuscript as deemed necessary and included citations for further details. This is a well-written manuscript.

There are no major revisions required, however, the details of the tests for validity and reliability of the outcome measurement tool need to be mentioned. The intervention procedure may be explained further in terms of intervention material and delivery. Though what constitutes the flipchart is mentioned, a table or a figure with the contents of each module in English Language will be useful.

In the results section, please mention if all participants attended six sessions (once per month for six months). The baseline characteristics were similar for both the groups except for the occupation. Authors may adjust for the inherent occupational differences in the intervention and control arm for the outcome. Consider doing a statistical analysis wherein you estimate the effect size.

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?

Yes

If applicable, is the statistical analysis and its interpretation appropriate?

Yes

Are all the source data underlying the results available to ensure full reproducibility?

Yes

Are the conclusions drawn adequately supported by the results?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Behavioural science, chronic disease epidemiology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 20 Jun 2022

Prasanna Mithra, Kasturba Medical College, Mangalore, Manipal Academy of Higher Education, Manipal, India

Reviewer Comments; followed by the response (in bold) by Authors:

Authors have rightly identified the research gap of paternal involvement in child care and nutrition. This was a randomized controlled trial to enhance the involvement of fathers in infant and young child feeding practices among those fathers identified to have poor involvement in child care in Dakshina Kannada District. The authors have described the methodology clearly in this manuscript as deemed necessary and included citations for further details. This is a well-written manuscript.

There are no major revisions required, however, the details of the tests for validity and reliability of the outcome measurement tool need to be mentioned. The intervention procedure may be explained further in terms of intervention material and delivery. Though what constitutes the flipchart is mentioned, a table or a figure with the contents of each module in English Language will be useful.

Thank you for your valuable suggestions and comments. We have now added detail on the test used for the reliability and validity of the data collection tool. We have now added a pictorial component describing the module content briefly. Also we have described the module delivery process for more clarity.

In the results section, please mention if all participants attended six sessions (once per month for six months).

We have added a sentence mentioning all participants having attended the sessions once a month for 6 months.

The baseline characteristics were similar for both the groups except for the occupation. Authors may adjust for the inherent occupational differences in the intervention and control arm for the outcome.

Thank you. We have now revised the statistical methods used for analyzing the effect of interventions and adjusted outcomes have been reported. We have used a linear mixed-effects regression model. The baseline differences were included in the model.

Consider doing a statistical analysis wherein you estimate the effect size.

Thank you for the suggestion. We have now done the analysis and estimated the effect size. The same has been mentioned in the data analysis description.

Competing Interests: No competing interests were disclosed.

Reviewer Report 23 May 2022

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Sathish Thirunavukkarasu 

Dept. of Family and Preventive Medicine, Emory University, Atlanta, GA, USA

This article by Mithra et al. examined the effectiveness of a module intervention in improving the involvement and practices of 120 fathers towards infant and young child feeding in a district in

Karnataka state, India. The manuscript addresses an interesting topic, and it is well written. However, as detailed below, I have some significant concerns about the statistical methods used for analyses.

1. Provide information on blinding participants and others involved in the trial, including those who conducted the analysis.
2. Three participants were lost to follow-up, and leaving them out of the analysis is not an intention-to-treat (IIT) analysis. I agree it is a tiny number, but it would be good to impute the missing data using some ideal techniques to satisfy the IIT principle.
3. The authors did not use appropriate statistical methods for the analyses. Paired 't' test does not consider the correlation between repeated measurements taken on the same individual over time and does not adjust for any baseline differences in covariates. In this study, occupation and the knowledge score were not balanced between the two arms (please don't rely on the statistical tests for baseline differences), and they were not adjusted for in the analyses. Finally, with 't' test one cannot say that the mean change in one arm was higher or lower than that in the other arm (which the authors claim). I suggest using mixed-effects linear regression models for the analyses.
4. Was there a possibility of contamination between study arms? If yes, how was it handled?
5. Why did the attitude score in the intervention group show lesser improvement than the knowledge and practice scores? Please provide some insights on this.

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?

Yes

If applicable, is the statistical analysis and its interpretation appropriate?

No

Are all the source data underlying the results available to ensure full reproducibility?

Yes

Are the conclusions drawn adequately supported by the results?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Chronic disease epidemiology, particularly diabetes.

I confirm that I have read this submission and believe that I have an appropriate level of

expertise to state that I do not consider it to be of an acceptable scientific standard, for reasons outlined above.

Author Response 20 Jun 2022

Prasanna Mithra, Kasturba Medical College, Mangalore, Manipal Academy of Higher Education, Manipal, India

Reviewer Comments; followed by the response (in bold) by Authors:

This article by Mithra et al. examined the effectiveness of a module intervention in improving the involvement and practices of 120 fathers towards infant and young child feeding in a district in Karnataka state, India. The manuscript addresses an interesting topic, and it is well written. However, as detailed below, I have some significant concerns about the statistical methods used for analyses.

Provide information on blinding participants and others involved in the trial, including those who conducted the analysis.

Thank you for your valuable suggestions and review. It was an open-label intervention. The nature of the intervention was not conducive to blind the participants or investigators. We have now specified the same in methodology.

Three participants were lost to follow-up, and leaving them out of the analysis is not an intention-to-treat (ITT) analysis. I agree it is a tiny number, but it would be good to impute the missing data using some ideal techniques to satisfy the ITT principle.

We have now used imputation for missing numbers and carried out ITT for all the outcome variables. A sentence is now added in this regard in the data analysis section. Data reanalysis is done and reported in the tables.

The authors did not use appropriate statistical methods for the analyses. Paired 't' test does not consider the correlation between repeated measurements taken on the same individual over time and does not adjust for any baseline differences in covariates. In this study, occupation and the knowledge score were not balanced between the two arms (please don't rely on the statistical tests for baseline differences), and they were not adjusted for in the analyses. Finally, with 't' test one cannot say that the mean change in one arm was higher or lower than that in the other arm (which the authors claim). I suggest using mixed-effects linear regression models for the analyses.

Thank you for the valuable suggestions and input. We have redone the data analysis using the mixed-effects linear model and reported the findings, to take care of the baseline differences across both arms. Also, we have now reported the adjusted mean scores for all the three outcome variables (adjusted for occupation and baseline knowledge scores). These have been now added to Table 2 to keep up the comprehensive structure and also to make it complete.

Was there a possibility of contamination between study arms? If yes, how was it handled?

Thank You. We chose the study areas for interventions from different taluks, to avoid contamination.

Why did the attitude score in the intervention group show lesser improvement than the knowledge and practice scores? Please provide some insights on this.

Both the groups had a higher attitude score in the baseline itself, so it showed the ceiling limit effect. A brief description in this regard has been added in the discussion section with an explanation for the same.

Competing Interests: No competing interests were disclosed.

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