

Effectiveness of a video-based intervention to improve the interpersonal communication skills of public health midwives in a district of Sri Lanka: a cluster randomised trial

S A S Prasanna ¹, H T C S Abeysena,² M A A P Alagiyawanna³

To cite: Prasanna SAS, Abeysena HTCS, Alagiyawanna MAAP. Effectiveness of a video-based intervention to improve the interpersonal communication skills of public health midwives in a district of Sri Lanka: a cluster randomised trial. *BMJ Public Health* 2024;**2**:e000331. doi:10.1136/bmjph-2023-000331

Received 30 June 2023
Accepted 19 August 2024

ABSTRACT

Objective To determine the effectiveness of a video-based intervention, the V-BIS, in improving the interpersonal communication skills (IPCS) of public health midwives (PHMs).

Design A cluster randomised trial.

Setting The setting is a Medical Officer of Health (MOH) area, the district's basic administrative unit in public health. The study was conducted at six MOH areas/clusters in a district of Sri Lanka between February and July 2020.

Participants PHMs who completed 6 months of working in the same setting were recruited.

Intervention The V-BIS intervention is a video-based intervention designed to improve the IPCS of PHMs.

Main outcome measures The primary outcome was the proportion of PHMs having good IPCS 1 month after the intervention. The secondary outcomes were (1) the proportion of PHMs having 'good IPCS' 3 months after the intervention and (2) the proportion of PHMs having 'good knowledge of complementary feeding (CF)' practices 1 month after the intervention.

Results Compared with the control group, the intervention group improved their IPCS by 33.0% at 1 month and 18.3% at 3 months after the intervention. The observed differences in skills between the groups were statistically significant at 1 month (adjusted OR=14.00, 95% CI 4.9 to 40.1) and 3 months (adjusted OR=5.52, 95% CI 1.81 to 16.9). Compared with the control group, the intervention group did not significantly improve good knowledge of CF practices 1 month after the intervention (OR=2.61, 95% CI 0.65 to 10.53).

Conclusions The V-BIS intervention effectively improves the IPCS of PHMs and can be used as a training intervention.

Trial registration number SLCTR/2020/006.

INTRODUCTION

Interpersonal communication (IPC) is a face-to-face interaction where information, meanings and feelings are shared between the communicator and the receiver.^{1,2} IPC includes verbal and non-verbal communication, with

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Communication skills training interventions, including videos and role-playing, are more effective in improving communication skills than traditional classroom-based lectures.

WHAT THIS STUDY ADDS

⇒ The V-BIS intervention, a video-based intervention designed to improve the IPCS of PHMs, significantly improved the interpersonal communication skills (IPCS) of public health midwives (PHMs) compared with the control group but did not significantly improve knowledge of complementary feeding. The IPCS gained from the intervention declined over time, indicating the need for regular training.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The V-BIS intervention is an effective method for improving the IPCS of PHMs.

over 60% of IPC comprising non-verbal communication. To conduct an effective IPC, the communicator must identify the receiver's verbal and non-verbal cues by paying attention to the receiver's physical, spiritual and social aspects during the discussion. For this, a communicator should be equipped with a set of verbal and non-verbal skills known as interpersonal communication skills (IPCS).^{3,4}

IPCS are not inborn skills but learnt ones. Although these skills can be taught, training a person in IPCS is a difficult task, and the skills that were taught can be easily forgotten if the learnt skills are not practised regularly.⁵ Among communication skills training interventions, a video-based intervention with skills improvement sessions has been identified as an effective method compared with traditional lecture-based training methods.^{6,7} Tailor-made training interventions that include



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¹Health Promotion Bureau, Ministry of Health Sri Lanka, Colombo, Sri Lanka

²University of Kelaniya Faculty of Medicine, Ragama, Sri Lanka

³Health Promotion Bureau, Colombo, Sri Lanka

Correspondence to

Dr S A S Prasanna;
samithaprasanna33@gmail.com

educational videos and skills improvement sessions like role-playing are recognised as effective methods used in the public health field to train health staff.^{8,9}

Public health midwives (PHMs) are the primary grassroots-level maternal and child healthcare providers within Sri Lanka's public health sector. Gampaha District has the highest population out of the 25 districts of the country, and 540 PHMs are working throughout the district.¹⁰ These PHMs provide field clinics and domiciliary care by communicating with their clients and delivering their services effectively.

There is a lack of data on the current level of IPCS among PHMs in Gampaha District. Observations suggest that PHMs have low levels of IPCS, compromising the quality of maternal care and childcare. Good IPCS are crucial to PHMs as these impact their ability to educate and support mothers on essential health practices, such as complementary feeding (CF). However, no studies have evaluated the IPCS among PHMs or any training intervention to improve the IPCS of PHMs in similar settings within Sri Lanka, making it challenging to address the issue adequately.

This scientifically sound study aims to fill this gap by assessing the effectiveness of a newly developed video-based intervention to improve IPCS among PHMs in Gampaha District. The findings will help create better training programmes, leading to enhanced IPCS of PHMs in the public health sector of Sri Lanka.

METHODS

Trial design and participants

A cluster randomised trial was conducted in Gampaha District, Sri Lanka, from February to July 2020. A Medical Officer of Health (MOH) area, the smallest administrative unit in the public health sector in Sri Lanka, was considered a cluster for this study. The intervention was delivered at the cluster level to avoid contamination with the control arms. Outcomes were measured at the participant level at 1 month and 3 months following the intervention. PHMs who had completed 6 months of work in the same MOH setting were recruited as study participants. PHMs who were on leave or attached to any other training programme outside the MOH area at the time of recruitment were excluded from the study.

Intervention

The intervention was V-BIS, a video-based training programme, tailored to address the IPCS challenges faced by PHMs. The training included 21 essential IPCS, encompassing both verbal and non-verbal communication skills crucial to an effective client-provider interaction, divided into three subcomponents: opening (eg, greeting and self-introduction), content (eg, using a pleasant tone, simple language, empathy and appropriate non-verbal cues) and ending (eg, summarising and encouraging enquiries).

The intervention includes lectures, educational videos, skills improvement role-plays and interactive discussions aimed at enhancing the IPCS of PHMs. It began with introductory lectures on IPCS, followed by the key messages of CF practices, which provided the basic subject knowledge for discussions during the training (30 min). Following this, two educational videos were shown: the first explained the effective usage of IPCS, and the second demonstrated improper usage of IPCS during client-provider interactions (40 min). After a short break, participants were divided into four groups. One volunteer from each group was selected to perform two role-play sessions depicting an interview between a PHM and a mother having an issue with her child's CF practices. Two of the four volunteers were given a role-play scenario guide to act as mothers, and the other two were given a guide to act as PHMs. The rest of the group members helped the volunteers develop their roles (15 min). Both role-play sessions were video-recorded (15 min each). The recorded videos were then screened and opened for discussion. The audience was encouraged to constructively critique the role-plays, highlighting positive aspects and improvement areas (30 min each). The intervention concluded with a review of the facts and points discussed during the training programme.

Considering the feasibility of implementing the training programme, the V-IBS was scheduled as a half-day training intervention, administered only once to the participants at the beginning of the study, and there were no multiple exposures during the study period of 3 months. Therefore, the PHMs in the intervention arm were exposed to the V-BIS intervention only once after the preassessment of the skills, while the PHMs in the control arm only received the usual inservice training provided in the MOH setting. All inservice training programmes conducted at the selected MOH setting during the study period were monitored, and it was confirmed that neither group was exposed to any training relevant to IPCS.

Outcomes

The study's primary outcome was the proportion of PHMs having good IPCS 1 month after the intervention. There were two secondary outcomes: (1) the proportion of PHMs with 'good IPCS' 3 months after the intervention and (2) the proportion of PHMs with 'good knowledge of CF practices' 1 month after the intervention.

The Interpersonal Communication Assessment Tool (IPCAT), an observer rating scale, was used to assess the IPCS of PHMs.¹¹ The IPCAT included a five-factor model with 22 items. The factors were 'engaging' (six items on making rapport), 'delivering' (four items on paying respect to the client), 'questioning' (four items on the proper way of asking questions), 'responding' (four items on empathy) and 'ending' (four items to assess the skills of ending a conversation productively). According to the developed 5-point scoring scale for the tool, the maximum total score that a participant could achieve was 110 marks (22 items × 5). A score of 3 or more on each

item indicated good IPCS. An individual who had good IPCS for all 22 items could achieve a total of 66 marks, which is 60% of the maximum score (110 marks). Therefore, 60% (66 marks) of the total score for the 22 items was taken as the cut-off point for good IPCS. Participants who scored less than 60% were categorised as having poor IPCS. The principal investigator (PI) consulted an expert in CF and developed a self-administered questionnaire to assess participants' knowledge of CF, with regard to the 10 key messages of CF practices.¹² PHMs who scored more than 75% on their knowledge of CF practices were categorised as having good knowledge of CF practices.

Sample size

The sample size for the intervention and control groups was calculated based on the assumption that the proportion of PHMs with good IPCS would be 0.31 in the control group and 0.62 in the intervention group.¹³ The significance level for calculating the sample size was 5%, with a power of 80%. The required sample size was calculated as an average of 38 PHMs per group. The average cluster size of the PHMs per MOH was 24, and the intra-cluster correlation was taken as 0.02.¹⁴ The design effect was 1.44. To account for non-respondents and loss to follow-up, an additional 10% was added to the sample size. The computed final sample size for each group was 61. The average number of PHMs in the MOH cluster in the district was 24. Therefore, to fulfil the sample size of each arm, only three clusters were selected for each group.

Randomisation and blinding

There are 15 clusters (MOH areas) in the district. Out of these 15 MOH clusters, 1 MOH area, with the lowest population and fewer PHMs, was excluded from the study. Each of the remaining 14 MOH clusters had an average of 24 PHMs. The PI paired these 14 MOH clusters into seven pairs based on their geographical proximity to avoid potential contamination of the intervention.

A person unaware of the pairing process of the seven clusters was used to select three pairs out of the seven pairs, as three MOH clusters needed to be chosen to fulfil the sample size of each group. The same person randomised the two MOH clusters in a selected pair into intervention and control groups by tossing a coin. The three clusters randomised to the intervention group consisted of 77 PHMs, while the three in the control group included 73 PHMs. This difference was due to the varying number of PHMs in each MOH cluster included in the study, resulting in different participant numbers for the intervention and control groups.

The V-BIS intervention was implemented on a cluster basis. First, the PI coordinated with the MOH doctor, who is the administrator of the MOH area, to schedule a convenient date and time during their inservice training days when all PHMs are available. All PHMs in the intervention arm were exposed to the intervention only once, by cluster. In this study design, the participants in both

groups were not blinded by their exposure status to the intervention.

The IPCS data of PHMs were collected by video-recording the PHMs' client-provider interactions. In real clinical settings, PHMs are busy and face many practical disturbances in the clinic environment, making it tedious and time-consuming to assess IPCS with real clients, often leading to errors. Real clients with different educational backgrounds and mental states do not consistently allow for testing all the aspects of IPCS within a short period of data collection. These challenges can be overcome by using simulated clients trained to facilitate the interview by reacting, behaving, showing feelings, and asking and answering questions to explore IPCS comprehensively. Many studies have used simulated clients in communication skills assessment because it is a cost-effective and feasible method for data collection.¹⁵⁻¹⁷ In this study, four women were trained as simulated mothers with a child having CF issues. Each PHM was introduced to a simulated client to conduct a discussion using their IPCS. Five simulated clients were randomly allocated among the PHMs to reduce selection bias.

The data collectors were trained in the video recording process, ensuring the completeness of the data in the questionnaires and understanding of the study objectives. Baseline data on IPCS and knowledge of CF of the participants in both groups were collected 1 month before the intervention. Postinterventional data on IPCS were collected 1 month and 3 months after the intervention, while knowledge of CF was collected 1 month after the intervention. All data collectors collecting sociodemographic, CF knowledge and IPCS data were blinded to the participant's exposure status to the intervention.

An independent rater, who was blinded to participants' exposure status, rated the recorded videos. After having proper training on IPCAT and its rating guide, the rater viewed the recorded videos, assigned marks for each item of the IPCAT and calculated a total score for each participant.

Statistical analysis

Data were analysed using SPSS V.20 software. The descriptive results of the study were presented as proportions, with variables not following the normal distribution presented as median values with respective IQR. The comparability of the proportions between the two groups was assessed using the χ^2 test. Logistic regression was the main analysis method, and the generalised estimating equation was used to adjust for baseline imbalances due to the clustering of participants within the clusters. The results were presented using OR, adjusted OR (AOR) and 95% CI.

Patient and public involvement

We did not involve patients or members of the public directly in designing, conducting, interpreting the results of the study or writing the manuscript.

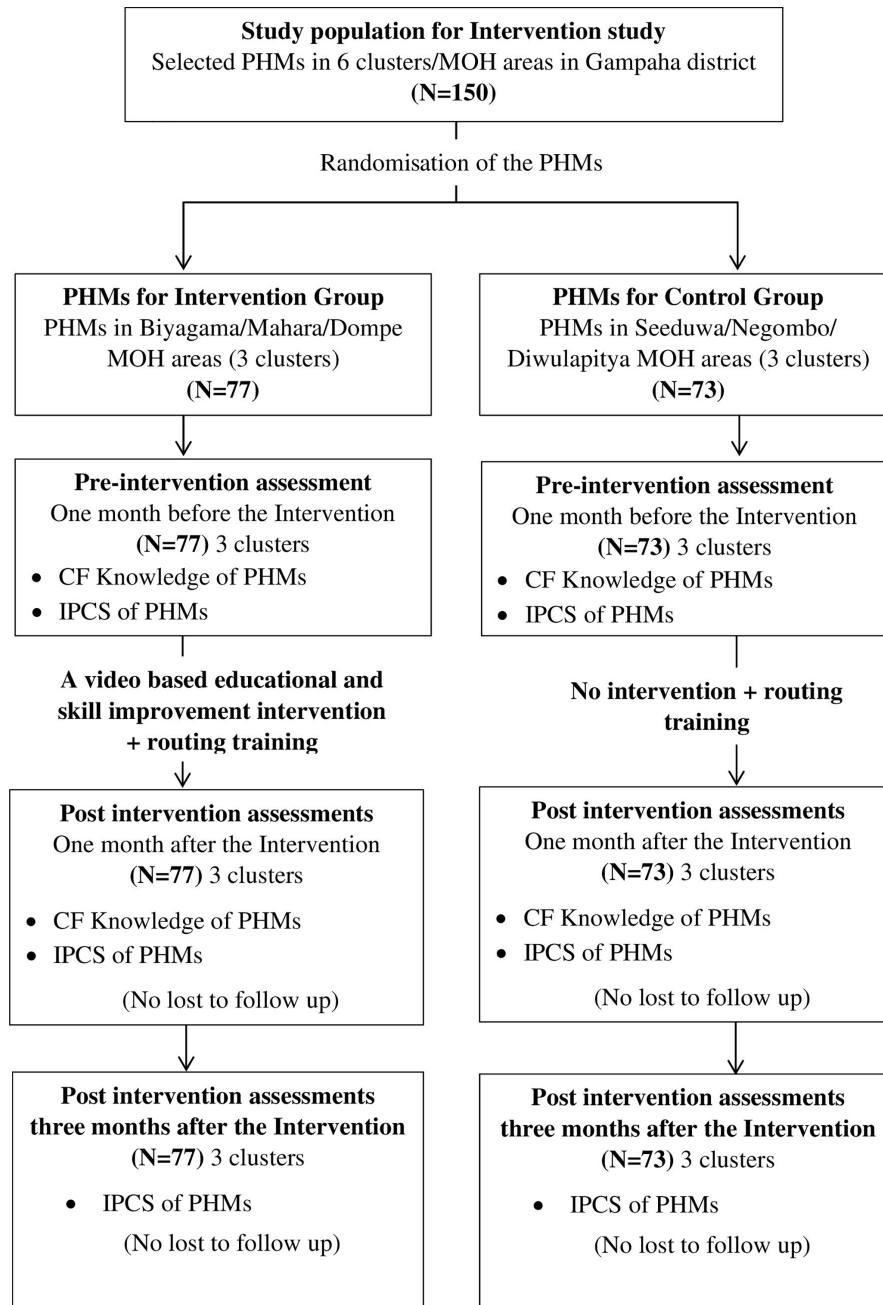


Figure 1 The CONSORT chart of the study. CF, complementary feeding; CONSORT, Consolidated Standards of Reporting Trials; IPCS, interpersonal communication skills; MOH, Medical Officer of Health; PHMs, public health midwives.

RESULTS

This study included 150 PHMs from six MOH clusters. The intervention group comprised three MOH clusters and included 77 participants: 26 PHMs from cluster 1, 23 PHMs from cluster 2 and 28 PHMs from cluster 3. The control group also had three clusters and included 73 participants: 23 PHMs from cluster 1, 25 PHMs from cluster 2 and 25 PHMs from cluster 3. All study participants who took part in the preintervention assessment proceeded to the postintervention assessments 1 month and 3 months after the intervention, with no loss to follow-up. Therefore, the response rate of the participants in both the preassessment and postassessment

phases was 100%. **Figure 1** shows the Consolidated Standards of Reporting Trials diagram.

The median age of PHMs in both groups was 40 years: the IQR for the intervention group was 37.0–53.0 and for the control group 35.0–52.0. Majority in both the control (n=60) and intervention (n=64) groups were Buddhist. The proportion of educational qualifications between the groups was similar, with no significant difference. Majority of the intervention (90.9%, n=70) and control (86.3%, n=63) groups were married at the time of the recruitment. Most participants in both groups had more than 9 years of service experience. Only 58.9% in the control group and 48.1% in the intervention group had

Table 1 Distribution of study participants according to selected sociodemographic characteristics in the intervention and control groups

Demographic variables	Control n (%)	Intervention n (%)	Level of significance
Age (years)			
≤34	16 (21.9)	9 (11.7)	
35–44	26 (35.6)	35 (45.5)	
45–54	19 (26.0)	18 (23.4)	
≥55	12 (16.4)	15 (19.5)	
Median (IQR)	40 (35.0–52.0)	40 (37.0–53.0)	
Religion			
Buddhist	60 (82.2)	64 (83.1)	$\chi^2=0.02$, df=1, p=0.88
Catholic	13 (17.8)	13 (16.9)	
Education			
Passed GCE (O/L)	6 (8.2)	6 (7.8)	$\chi^2=0.01$, df=2, p=0.99
Passed GCE (A/L)	44 (60.3)	47 (61.0)	
Got degree/diploma	23 (31.5)	24 (31.2)	
Marital status			
Unmarried	7 (9.6)	6 (7.8)	$\chi^2=1.67$, df=3, p=0.64
Currently married	63 (86.3)	70 (90.9)	
Divorced	0 (0)	0 (0.0)	
Widowed	2 (2.7)	1 (1.3)	
Duration of service (years)			
≤9	28 (38.4)	19 (24.7)	$\chi^2=3.761$, df=2, p=0.153
10–19	24 (32.9)	35 (45.5)	
≥20	21 (28.8)	23 (29.9)	
Training on IPCS			
Training	43 (58.9)	37 (48.1)	$\chi^2=1.77$, df=1, p=0.18
No training	30 (41.1)	40 (51.9)	
Total	73 (100)	77 (100)	

A/L, Advanced Level; GCE, General Certificate of Education; IPCS, interpersonal communication skills; O/L, Ordinary Level.

been exposed to IPCS training during the past 3 years. **Table 1** shows the sociodemographic characteristics of the participants.

Participants' knowledge of CF practices was skewed during the preinterventional assessment. Both groups had a median score of 85.7% for knowledge of CF practices (IQR: 78.5–88.0). Participants with good knowledge of CF practices comprised 86.3% (n=63) of the control group and 88.3% (n=68) of the intervention group. The comparison of the proportions of knowledge between the two groups did not show a statistically significant difference (p=0.71). After 1 month of the intervention, the median score on knowledge of CF practices for both groups was 88.0% (IQR: 85.7–92.8). In the intervention and control groups, 96.1% (n=74) and 90.4% (n=66) of the participants had good knowledge of CF. The improvement in good knowledge of CF in the intervention group was 5.7% higher compared with the control group, but this difference was not statistically significant (OR=2.61, 95% CI 0.65 to 10.53).

The IPCS scores of PHMs in the samples were not normally distributed at the preinterventional assessment. Both groups had a median score of 48 marks (IQR: 41–63) for IPCS, indicating a low level of IPCS in both groups. The proportion of PHMs with good IPCS was 12.3% (n=9) in the control group and 13.3% (n=11) in the intervention group. There was no statistically significant difference in IPCS between the groups (p=0.72) before the intervention.

One month after the intervention, 51.9% (n=40) of the intervention group had good IPCS compared with 9.6% (n=7) in the control group. This difference indicates a 33.0% improvement in good IPCS in the intervention group compared with the control group 1 month after the intervention. The observed differences in skills between the intervention and control groups 1 month after the intervention were statistically significant (AOR=14.00, 95% CI 4.9 to 40.1), even after adjusting for baseline imbalances in (1) IPCS, (2) knowledge of CF practices, (3) service duration and (4) prior training on IPCS.



Three months after the intervention, 31.2% (n=24) of the participants in the intervention group had good IPCS compared with 12.3% (n=9) in the control group. The skills improvement in the intervention group was 18.9% higher than the control group 3 months after the intervention, and this difference was also statistically significant even after adjusting for the baseline imbalances mentioned above (AOR=5.52, 95% CI 1.81 to 16.9). Table 2 shows the comparison of the groups using the proportion of IPCS and knowledge of CF practices.

DISCUSSION

Principal findings

The V-BIS intervention significantly improved the IPCS of PHMs. Compared with the control group, good IPCS in the intervention group improved by 33.0% at 1 month and 18.3% at 3 months after the intervention. However, compared with the control group, good knowledge of CF in the intervention group did not significantly improve at 1 month after the intervention.

Strengths and limitations

The strengths of this study included its rigorous cluster randomised trial design, which minimised potential contamination between the intervention and control groups. The contamination bias in this trial was controlled during the cluster selection stage. The MOH clusters in the district were paired based on their geographical distance, and this non-bordering cluster pairing method minimised the contamination of the intervention with the control group. Additionally, the impact of contamination in this study was very low as PHMs had no opportunities to gather and discuss training-related topics due to their busy working schedule. A person unaware of the cluster pairing method selected six clusters and randomised them into the intervention and control groups. This sampling method ensured the concealment of allocation, minimising selection bias.

The study facilitated the IPCS assessment in direct observation by using simulated clients who miss the active participation of real clients in data collection. Using simulated clients to assess IPCS provided a controlled environment, allowing for consistent and comprehensive evaluation of communication skills, which might have been difficult in real clinical settings. However, simulations amplify existing inequalities, stereotypes or prejudices in the scenarios used, leading to information bias.¹⁶ Direct observations were conducted by video-recording the client-provider interactions. The Hawthorne effect is another identified bias during this type of data collection method, as study participants tend to overperform when they know they are being observed, which can mask their actual skill level.¹⁸ To minimise this effect, several measures were taken. Participants were assured of data security and were informed that the study results would not affect their future career development. PHMs were advised to interact naturally with the provided client as

Table 2 Comparison of the intervention group and the control group using the proportion of IPCS and knowledge of CF practices 1 month before and 1 month and 3 months after the intervention

	Preintervention		Postintervention				AOR (95% CI)
	Control n (%)	Intervention n (%)	1 month after		3 months after		
			Control n (%)	Intervention n (%)	Control n (%)	Intervention n (%)	
Knowledge of CF practices							
Poor knowledge	10 (13.7)	9 (11.7)	7 (9.6)	3 (3.9)	64 (87.7)	53 (68.8)	2.61 (0.65 to 10.53)
Good knowledge	63 (86.3)	9 (11.7)	66 (90.4)	74 (96.1)	9 (12.3)	24 (31.2)	
Level of IPCS							
Poor IPCS	64 (87.7)	66 (85.7)	66 (90.4)	37 (48.1)	64 (87.7)	53 (68.8)	5.52 (1.81 to 16.9)
Good IPCS	9 (12.3)	11 (13.3)	7 (9.6)	40 (51.9)	9 (12.3)	24 (31.2)	
Total	73 (100)	77 (100)	73 (100)	77 (100)	73 (100)	77 (100)	

AOR, adjusted OR; CF, complementary feeding; IPCS, interpersonal communication skills.

they would in their clinics. The video recording team was instructed to arrange the recording equipment inside the consultation room before commencing the interviews. The data collectors were advised not to be inside the room during the discussion and to maintain a comfortable environment for the PHMs to feel that they were not being observed.

One of the significant findings of this study was the substantial improvement in IPCS among PHMs in the intervention group, which was sustained, although reduced, at 3 months postintervention. This positive effect could be attributed to the comprehensive and context-specific design of the V-BIS intervention, which included practical components such as role-plays and video demonstrations. However, the wide CIs observed in some findings suggested a potential influence of other unmeasured factors. Despite this, the statistically significant improvements indicated that the V-BIS intervention had a meaningful impact on enhancing IPCS among PHMs. This substantial improvement in IPCS among PHMs suggests that the V-BIS intervention could be a valuable addition to the existing training curriculum for healthcare providers in Sri Lanka. Integrating this video-based training into regular inservice training sessions could help sustain the skills gained and underscores the need for ongoing training and periodic skills reinforcement to ensure lasting improvements in communication skills.

This study had a short follow-up period, which was limited to 3 months due to logistic issues. This short follow-up period did not cause selection bias from cluster or individual withdrawals, preventing loss to follow-up. Additionally, this short follow-up period minimised the bias due to the maturation effect of the intervention.

Participants in this study could not be blinded to their exposure status, which was identified as a limitation. Awareness of their exposure status could affect the study's outcome, causing information bias. However, the rater who evaluated the recorded videos was blinded to the participants' exposure status, minimising interviewer bias. Blinding was also applied during data entry, with a data entry person unaware of the participants' exposure status, thus avoiding information bias.

Comparison with other studies

Samaranayake⁸ conducted a local study of midwives in labour rooms. The training intervention included educational videos and skills improvement role-play sessions, similar to the current study. The primary differences between the interventions in Samaranayake's study and the current study were the training content, duration and frequency, with Samaranayake's study incorporating multiple training sessions. Samaranayake's study, which was hospital-based, reported 'good communication skills' levels that were twice as high as those found in the current study. This local study employed a pre and post quasi-experimental study design that measured the postintervention

skills improvement at 3 months (45%) and 6 months (52%). The second rating in Samaranayake's study showed improved skills compared with the first rating, which contradicts the results of the current study. The higher skills improvement in the second rating might be due to the maturation effects of the intervention, as Samaranayake's study had a long follow-up period that is not identified in the current study. Additionally, the current study reported a lower skills improvement (18.3%) after 3 months of the intervention, whereas Samaranayake's study showed more than double the improvement (45.7%) at the same time point. This discrepancy in skills improvement may be attributed to the multiple intervention exposures in Samaranayake's study compared with the single exposure in the current study and the lack of ongoing reinforcement of the skills acquired during the intervention. Without regular inservice training sessions and continuous support, the PHMs may have gradually lost the proficiency they initially gained. This highlights the necessity of integrating the V-BIS intervention into a continuous training programme curriculum, including periodic refreshers and monitoring, to maintain and further develop IPCS over time.

A training programme developed by Hausberg *et al.*¹⁹ including lectures and role-playing without a video demonstration, revealed a considerable improvement in the participants' IPCS. Another intervention designed to improve medical students' communication skills included similar components, such as educational videos and role-play sessions.²⁰ The current study's intervention was comparable to another intervention designed for healthcare workers, featuring a similar skills improvement component: trainee-guided feedback session after watching the peer's recorded role-plays.²¹ A different training module for dental students included direct interactions with actual patients without lectures or role-playing, and this study also showed significant skills improvement compared with the current study.²²

Another video-based communication skills training module that included video demonstrations, patient simulations and role modelling showed significant improvement in the knowledge but not in the skills, which contradicted the results of the current study. This study reported significantly higher scores in knowledge and skills than the control group 1 year after the intervention. This observed long-term results in that study may be due to the maturation effect of the intervention, which cannot be observed in the current study as it had a short follow-up period.⁹ A new intervention developed to improve doctors' communication skills using computer-based video clips also showed a significant improvement in IPCS, similar to the enhancement seen in the current study.²³

The V-BIS intervention selected a commonly used topic by the PHMs as the subject knowledge of the discussions in training. The results of the current

study showed that both the intervention and control groups had good knowledge of CF before the intervention, indicating that the IPCS results of PHMs were not affected by the level of knowledge of the subject being discussed during the interviews.

CONCLUSION

PHMs in Gampaha District, Sri Lanka, exhibited a low level of IPCS. The V-BIS intervention proved to be effective in improving the IPCS of PHMs. However, the IPCS gained from the intervention declined over time, indicating the need for regular inservice training at MOH setting using the V-BIS intervention and periodic monitoring. To ensure long-term effectiveness, it is recommended that the V-BIS intervention be integrated into a comprehensive training curriculum for PHMs. This integrated approach would reinforce IPCS and support sustainable skill development.

Acknowledgements We extend our gratitude to all experts and the participants involved in the study, as well as the central and regional health authorities who gave the permission and support to conduct the study.

Contributors SASP: guarantor and principal investigator, planned the research, conducted data collection and analysis, and wrote the manuscript. HTCSA: supervised the planning and analysis of the data and approved the final manuscript. MAAPA: supervised the planning of the research and approved the final manuscript.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Ethics approval Ethical clearance for the study was approved by the Ethics Review Committee, Faculty of Medicine, University of Kelaniya, Ragama, Sri Lanka (ref no: p/230/09/2017). All methods were conducted in accordance with the ethical standards of the Ethics Review Committee, following relevant guidelines and regulations. Informed written consent was obtained from all participants. We have also registered this study in the Sri Lanka Clinical Trials Registry, Sri Lanka Medical Association, 06, Wijerama House, Wijerama Mawatha, Colombo 08 (Reg. no – SLCTR/2020/006).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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ORCID iD

S A S Prasanna <http://orcid.org/0000-0001-6341-9181>

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